



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 29, 2020

Heidi Popelka
Senior Regulatory Specialist II
Ecolab, Inc.
1 Ecolab Place
St. Paul, MN 55102

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: FSC 35K
EPA Registration Number: 1677-256
Application Date: March 24, 2020
Decision Number: 561526

Dear Ms. Popelka:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.


2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Feline Calicivirus (surrogate for Norovirus) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

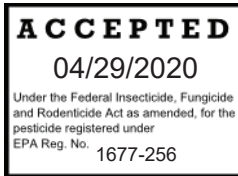
Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,



Steven Snyderman, Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: stamped label



04/28/2020

FSC 35K

Detergent-Disinfectant/Bactericide/Virucide*/Deodorizer/Fungicide/Mildewcide

(Note to agency: Text appearing in parentheses is optional text)

**(HOSPITALS)(MEDICAL ENVIRONMENT DISINFECTANT)(HOSPITALITY)
(HOTELS)(NURSING HOMES)(INSTITUTIONS)(SCHOOLS)
(RESTAURANTS)(FOOD SERVICE)(BEVERAGE AND FOOD PROCESSING
PLANTS)(VETERINARY AND INDUSTRIAL USE) (DISINFECTANT)(NON-FOOD
CONTACT SANITIZER)(CLEANER)(VIRUCIDAL*), (BACTERICIDAL),
(GERMICIDAL) (HOSPITAL USE DISINFECTANT)(DEODORIZER) (ODOR
COUNTERACTANT)(ODOR NEUTRALIZER), (CLEANS, DISINFECTS &
DEODORIZES)(SANITIZES NON-FOOD CONTACT SURFACES)(KILLS 99.9%
GERMS)(KILLS GERMS)(For AUTOMATIC DILUTION)(CONCENTRATE)(FOR
INSTITUTIONAL USE)(FOR INDUSTRIAL AND INSTITUTIONAL USE)**

For Hospital, Health Care, Commercial, Institutional, Industrial

Active Ingredients:

| | |
|---|----------------|
| Alkyl (C14, 50%; C12, 40%; C16, 10%) Dimethyl benzyl ammonium chloride..... | 1.63% |
| Octyl decyl dimethyl ammonium chloride..... | 1.22% |
| Didecyl dimethyl ammonium chloride..... | 0.74% |
| Dioctyl dimethyl ammonium chloride..... | 0.49% |
| Other Ingredients | 95.92% |
| Total: | 100.00% |

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

PELIGRO: Si usted no puede leer ingles, pida ayuda y pregunte sobre el contenido y las instrucciones de uso antes de emplear este producto.

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: Corrosive. Causes irreversible eye damage and severe skin irritation. Harmful if inhaled, swallowed, or absorbed through the skin. Do not get in skin, eyes, or on clothing. Wear rubber or chemical resistant gloves, long sleeved shirt, long pants, socks, and shoes, and protective eyewear such as safety glasses or goggles. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

If inhaled: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

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. Call a poison control center or doctor for treatment advice.

If on skin or on 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 for treatment advice. Have the person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

EMERGENCY MEDICAL INFORMATION CALL:

1-800-328-0026 (In the United States and Canada)

1-651-222-5352 (If located outside North America, call collect)

Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.

Note to physician: Probable mucosal damage may contraindicate the use of gastric lavage.

[Note to Reviewer: For containers of 5 gallons or more, the following Environmental Hazards language will appear on the final product label.]

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing the 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 the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product in your sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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.

This product is not for use on food contact surfaces.

This product [insert name] is a (hospital-use) ("one step") disinfectant (germicidal) (fungicidal) (mildewcidal) cleaner (and odor counteractant) (, bactericide and virucide) designed for (daily) general cleaning and disinfecting of hard, non-porous, environmental surfaces.

This product [insert name] is phosphate free, and effective in up to 400 ppm hard water.

This product [insert name] contains surfactants that generate foam when applied as directed by (sprayer) (pump sprayer) (pump-up sprayer).

(Please [refer to] [see] reference sheet for [additional] [directions for use] [information]).

(See [back], [side], [inner] [other] [fold-out] [booklet] [product container] [label(s)] [panel(s)] [container] for [complete] [additional] [information] [directions for use] [precautionary statements] [and] [first aid] [and] [storage and disposal]).

This product [insert name] is recommended for (daily) use for disinfecting and cleaning washable hard non-porous (environmental) surfaces including:

- Bathrooms, shower rooms and spas

- Shower stalls, tubs, tiles, shower doors, shower curtains, restroom fixtures, urinals, restroom floors
- Bathroom fixtures, sinks, exterior surfaces of toilets
- Non-food contact surfaces of coolers
- Glazed tile
- Linoleum, plastic (such as polyethylene, polypropylene, polyvinylchloride)
- Chrome, glazed porcelain, stainless steel, glass
- Walls

This product [insert name] is not recommended for use on marble.

This product [insert name] is recommended for use as a non-food contact surface sanitizer.

This product concentrate must be (diluted) (dispensed) through a closed loop system.

Areas of Use: hospitals, nursing homes, other healthcare facilities, schools and colleges, veterinary clinics and animal life science laboratories, industrial facilities, beverages and food processing plants, restaurants, hotels, motels, office buildings, recreational facilities, retail and wholesale establishments, animal care and rearing facilities, cruise ships, casinos, correctional facilities, athletic facilities, health clubs.

DISINFECTION:

For hospital disinfection and cleaning of hard non-porous surfaces according to the AOAC Germicidal Spray Test method in 400 ppm hard water, in the presence of 5% blood serum and 0.005% soap residue. Apply [insert name] a coarse spray by (sprayer) (pump sprayer) (or) (pump-up sprayer) to hard non-porous surfaces only, thoroughly wetting surfaces. All surfaces must remain wet for 5 minutes.

PREPARATION OF USE SOLUTION:

For use as a (Daily) Cleaner or (Daily) Restroom / Shower Cleaner:

Dilute at 1:64 (2 oz) – 1:21.3 (6 oz) per gallon of use solution. Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous surfaces only, thoroughly wetting surfaces with a (sprayer) (pump sprayer) (or) (pump-up sprayer). (Wipe surfaces with damp cloth or sponge). Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

For use as a (Daily) Disinfectant/Cleaner or (Daily) Restroom / Shower Disinfectant / Cleaner:

Dilute at 1:32 (4 oz) – 1:21.3 (6 oz) per gallon of use solution. Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous surfaces only, thoroughly wetting surfaces with a (sprayer) (pump sprayer) (or) (pump-up sprayer). All surfaces must remain wet for 5 minutes. (Wipe surfaces with damp cloth or sponge). Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

For use as a (Heavy Duty) Disinfectant/Cleaner or (Heavy Duty) Restroom / Shower Disinfectant/ Cleaner:

Dilute at **1:21.3 (6 oz)** per gallon of water. Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous surfaces only, thoroughly wetting surfaces with a (sprayer) (pump sprayer) (or) (pump-up sprayer). All surfaces must remain wet for 5 minutes. Wipe surfaces with damp cloth or sponge. Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

Toilet Bowl Cleaning and Disinfection:

Clean toilets by applying (4 oz.) - (6 oz.) of product per 1 gallon of use solution to all outer toilet surfaces, around the bowl, and up under the rim. Stubborn stains may require brushing. To disinfect the outer toilet surfaces, apply (4 oz.) - (6 oz.) of product per 1 gallon of use solution to the surface, thoroughly wetting surfaces with a pump sprayer (pump-up sprayer). All surfaces must remain wet for 5 minutes. Wipe outer toilet surfaces with a damp cloth or sponge.

BACTERICIDAL in 5 minutes at 1:32 dilution, 4 oz/gal – 1:21.3 dilution, 6 oz/gal diluted in 400 ppm hard water against the following pathogenic bacteria according to the AOAC Germicidal Spray Test modified in the presence of 5% blood serum and 0.005% soap residue (sodium stearate). Apply Use Solution by coarse spray using a (sprayer) (pump sprayer) (pump-up sprayer) 6 – 8 inches from surface.

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

Proteus vulgaris (NCTC 4635)

Serratia marcescens (ATCC 14756)

Streptococcus pyogenes (ATCC 19615)

Antibiotic-Resistant Bacteria:

Escherichia coli O157:H7 (ATCC 43895)¹

Staphylococcus aureus (CA-MRSA) (ATCC BAA-1683)

Staphylococcus aureus (MRSA) (ATCC 33592)¹

¹ for bactericidal activity against *Escherichia coli* O157:H7 (ATCC 43895) and *Staphylococcus aureus* (MRSA) (ATCC 33592) product must be diluted at 6 oz/gal.

For use as a Virucide*: Dilute at 1:32 dilution, 4 oz - 1:21.3 dilution, 6 oz per gallon of use solution. Pre-Clean heavily soiled areas. Apply Use Solution by coarse spray using a (sprayer) (pump sprayer) (pump-up sprayer) to hard, non-porous surfaces only, thoroughly wetting surfaces. All surfaces must remain wet for 5 minutes, unless otherwise directed. (Rinse surfaces with damp cloth or sponge). (Rinse surface with potable water). Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

***VIRUCIDAL** in 5 minutes at 1:32 dilution (4 oz/gal) - 1:21.3 dilution (6 oz/gal diluted in 400 ppm hard water against the following viruses according to the Virucidal Qualification Test modified in the presence of 5% blood serum and 0.005% soap residue (sodium stearate). Apply Use Solution by coarse spray using a (sprayer) (pump sprayer) (pump-up sprayer) 6 – 8 inches from surface.

*Hepatitis B Virus

*Hepatitis C Virus

*Herpes Simplex Virus Type 1 (ATCC VR-733)

*Herpes Simplex Virus Type 2 (ATCC VR-734)

*Human Coronavirus (ATCC VR-740)

*Influenza A Virus H1N1

*Influenza B Virus (ATCC VR-823)

*Murine Norovirus (Strain MNV-1.CW1)

*Respiratory Syncytial Virus (RSV) (ATCC VR-26)

*Human Immunodeficiency Virus Type 1 (Strain HTLV-111_B) (HIV-1)

For use as a Virucide for Norovirus (Feline Calicivirus) (ATCC VR-782)*: Dilute at 1:21.3 dilution, 6 oz per gallon of use solution. Pre-Clean heavily soiled areas. Apply Use Solution by coarse spray using a (sprayer) (pump sprayer) (pump-up sprayer) to hard, non-porous surfaces only, thoroughly wetting surfaces. All surfaces must remain wet for 5 minutes, unless otherwise directed. (Rinse surfaces with damp cloth or sponge). (Rinse surface with potable water). Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

***Norovirus (Feline Calicivirus) (ATCC VR-782) VIRUCIDAL** in 5 minutes at 1:21.3 dilution (6 oz/gal diluted in 400 ppm hard water against the following viruses according to the Virucidal Qualification Test modified in the presence of 5% blood serum and 0.005% soap residue (sodium stearate). Apply Use Solution by coarse spray using a (sprayer) (pump sprayer) (pump-up sprayer) 6 – 8 inches from surface.

***KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED 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 the transmission of Human Immunodeficiency Virus Type 1 (Strain HTLV-111_B) (HIV-1)(associated with AIDS).

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

Personal Protection: Clean-up must always be done wearing disposable protective gloves, gowns, masks and eye protection.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

Contact Time: Allow surface to remain wet for 5 minutes.

Disposal of Infectious Material: Blood, body fluids, cleaning materials and other clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

For use as a Fungicide: This product is effective against *Trichophyton interdigitale* (Athlete's Foot fungus) (ATCC 9533) and *Candida albicans* (ATCC 10231) when used at 1:32 dilution, 4 oz - 1:21.3 dilution, 6 oz per gallon of use solution. Apply as directed in the Disinfection / Cleaning Deodorizing directions for use.

For use as a Mildewcide: This product is effective against *Aspergillus niger* (ATCC 6275) when diluted at 1:32 dilution, 4 oz - 1:21.3 dilution, 6 oz per gallon of use solution at a contact time of 5 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

NON-FOOD CONTACT SURFACE SANITIZING:

Dilute at 1:32 dilution, 4 oz - 1:21.3 dilution, 6 oz per gallon of use solution. This product is an effective sanitizer against *Enterobacter aerogenes* (ATCC 13048), and *Staphylococcus aureus* (ATCC 6538) on hard, non-porous environmental surfaces only. Apply product by coarse spray using a (sprayer) (pump sprayer) (pump-up sprayer) (wet cloth,) (mop,) (scrubber,) (or) (by soaking). Treated surfaces must remain wet for 60 seconds. (Rinse and) dry with sponge, squeegee, mop or cloth or allow to air dry. Prepare a fresh solution at least daily or sooner if solution becomes diluted or soiled.

VETERINARY OFFICES: Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Dilute at 1:32, 4 oz - 1:21.3, 6 oz per gallon of water. Saturate the surfaces for a period of 5 minutes. Wipe or allow to air dry. Saturate all hard, non-porous animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Rinse all surfaces that come in contact with food, including equipment used for feeding and watering, with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARN, 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. Dilute at 1:32, 4 oz - 1:21.3, 6 oz per gallon of water. Saturate all hard, non-porous animal restraining equipment, as well as forks, shovels, and scrapers used for removing litter and manure for a period of 5 minutes. 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.

STORAGE AND 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:

(For containers 5 gallons or less.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

(For containers >5-55 gallons.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat procedure two more times. Then offer for recycling or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by incineration.

| |
|----------------------|
| <p>Net Contents:</p> |
|----------------------|

| |
|---|
| <p>2.5 US GAL (9.5 L) 0.52 US GAL (2.0 L) 0.34 US GAL (1.3 L)</p> |
|---|

(Refer to SDS for further information.)

(Expiry Date:)

(Country of Origin:)

(Manufacturing Date:)

()

(KEEP FROM FREEZING)

This product may be patented: www.ecolab.com/patents

Manufactured by:

Ecolab Inc.

1 Ecolab Place

St. Paul, MN 55102-1390

www.ecolab.com

EPA Reg. No. 1677-256

EPA Est. No.: 1677-MN-1 (P), 60156-IL-1 (SI), 1677-CA-2 (R),

1677-TX-1 (D), 1677-IL-2 (J), 1677-CA-1 (S), 1677-GA-1 (M),

1677-WV-1 (V), 58046-TX-2 (X), 6574-KY-1 (CA)

Superscript refers to first letter of date code

Optional Marketing Language

Note: Bold, italicized text is information for the reader and is not part of the label.

[Bracketed information is optional text.]

Makes x gallons of use solution when diluted according to label directions.

Claims (for cleaning, deodorizing, stain removal):

- New
- New Formula
- Daily-Use [Cleaner] [Spray]
- No filming
- Fresh Scent
- Fragrance Free (*at least one alternate CSF will have 0% fragrance*)
- Freshens
- Freshens/Deodorizes as you clean
- Leaves [bathroom(s)] [restroom(s)] [surfaces] [clean and] sanitary
- Leaves [bathroom(s)] [restroom(s)] [surfaces] [clean and] fresh
- Cleans to a streak-free shine [surfaces] [faucets] [countertops] [exterior surfaces of appliances] [stainless steel] [and shiny surfaces]
- Cleans [commercial] [industrial] [institutional] [hard] surfaces to a streak-free shine
- Cleans tough messes
- Deodorizer
- Deodorizes
- Deodorizes and has a clean, fresh scent
- Eliminates odors caused by [bacteria]
- Removes odors
- Removes – and/or – cleans – and/or- cuts through –and/or – [tough] stains
 - bathroom [restroom] dirt – and/or – stains [while leaving a streak-free shine]
 - grime [while leaving a streak-free shine]
 - [tough] – and/or– soil(s) [while leaving a streak-free shine]
- Powerful restroom \ bathroom cleaner
- Penetrates [and dissolves] tough soap scum and hard water stains [without scrubbing]
- Penetrates tough restroom \ bathroom soils without scrubbing
- Non-abrasive
- Safely cleans most surfaces
- Designed to improve cleaning productivity
- No scrubbing

- Do not freeze
- Minimizes training time
- Fewer products – no need for separate deodorizer
- Non-abrasive [formula][won't scratch surfaces]
- Rinses away easily
- Scum buster formula
- Heavy duty formula
- Makes employee tasks \ job \ life simple \ easy
- Powers away soap scum and hard water stains in one step
- Cleans [and] [shines] [and] [deodorizes] [washable] [restroom \ bathroom] [surfaces] [and] [fixtures]
- Cleans without scrubbing
- Restrooms – great all-around restroom \ bathroom cleaner
- Makes employee tasks simple cutting through soap scum [and] [hard water stains]
- Designed to help improve cleaning productivity
- Saves time – little to no scrubbing needed!
- Minimizes training time
- Reduces steps necessary to clean [and] [disinfect] the [restroom] [bathroom] [surfaces]
- Labor Savings
- Improved Efficiency
- Positive User Experience

Claims (sanitizing)

- Sanitizes hard, nonporous surfaces
- Sanitizer
- Cleaner / Sanitizer
- Sanitizing Cleaner
- Cleans and sanitizes
- Leaves surfaces [clean and] sanitized
- Kills 99.9% of bacteria

Claims (disinfection)

- Antibacterial [action]
- Bacteria-fighting – or – Germ*-fighting formula
- Bactericidal
- Restroom – and/or- Bathroom disinfectant
- Broad spectrum disinfectant [cleaner]
- Cleans and disinfects
- Cleaner and disinfectant in one when following disinfection use directions
- Cleans –and/or- disinfects [bathroom] [restroom]
- Disinfects [and deodorizes]
- Disinfects as it cleans when following the disinfection use directions
- Disinfects nonporous [hard] surfaces
- [Effective] [bathroom – and/or-restroom] disinfectant –and/or-cleaner
- [Effective] disinfectant [in presence of 5% serum load – or- organic soil]
- Germicide* – or- Germicidal*
- Kills odor-causing bacteria
- 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.
- Meets AOAC efficacy standards for hospital disinfectants
- Medical Environment Disinfectant
- Mildewcidal
- One step cleaner & disinfectant
- Removes stains and disinfects
- This [cleaner] [disinfectant] combines cleaning and disinfecting [in one product] [in one step] when following the disinfection use directions
- This product is a cleaner disinfectant which combines cleaning, disinfecting and stain removal in one product when following the disinfection use directions
- [This product] The power to clean [tough] [bathroom –and/or- restroom] [grime] [dirt] [soils] and kill bathroom germs –and/or- bacteria
- *Virucide/*Virucidal
- Kills 99.9% of germs
- Scrub-free disinfectant

Claims – General

- New[!] **to be used for first 6 months only**
- [Removes] [Eliminates] [Attacks] [Gets rid of] [Melts away] tough [[bathroom –and/or- restroom – and/or- hotel room] [dirt] [soils] [grime]] [!]
- Tough on [soap scum – and/or – lime buildup – and/or – hard water film – and/or - film]
- Commercial Product[s]
- See side/back panel for First Aid...
- Institutional [size] [use]
- Developed \ Formulated \ Designed for [institutional][hospital] [restroom \ bathroom] use
- This product \ Product name complies with consumer volatile organic compound (VOC) \ VOC laws
- [Contains] No Bleach
- [Contains] No Phosphorus
- **For closed chemical container only:**
- Tamper proof bottle
- Bottle \ Sealed bottle \ Container \ Closed chemical system designed for employee safety
- Bottle \ Sealed bottle \ Container \ Closed chemical system designed to prevent spills and accidental concentrate \ product exposure

USE LOCATIONS: [Where to use this product] [For use around –or- in –or- throughout the]

- Bathroom[s]
- Hospital[s]
- Hotel[s]
- Locker Room[s]
- Public Restroom[s]
- Shower – and/or – Bath Area[s]
- Spa[s]

- Medical environments
- Nursing homes
- Operation rooms
- Isolation wards
- Medical research centers
- Schools
- Colleges
- Dormitories
- Day Care centers
- Nurseries
- Super markets
- Convenience stores
- Office buildings
- Funeral homes
- Laboratories
- Recreational Facilities
- Health clubs
- Household areas
- Kitchen exteriors \ exterior surfaces
- Bathrooms \ restrooms
- Veterinary clinics
- Kennels
- Breeding and grooming establishments
- Pet \ animal quarters
- Zoos
- Pet shops
- Churches
- Manufacturing facilities
- Military installations
- Factories
- Motels

USE SITES: [Use] On [hard,] [nonporous surfaces] [the product will not damage]

- [Bath] Tubs
- Bathroom Tile
- Counters/Countertops
- Doorknobs
- Faucets
- Fixtures [Chrome] [Steel]
- Floors [No Wax – and/or- Washable]
- Garbage [Can] [Pail]
- Recycling Bin[s]
- Shower [curtain] [curtains] [stalls] [floors] [walls and doors]
- Sink[s]
- Stand[s]
- Toilet[s] [exterior][rims]
- Tubs
- Urinal[s]
- Vanity [Top]
- [Washable] Railings
- Walls

USE SURFACES:

- Baked Enamel
- Chrome
- Enamel
- Formica
- Glass [Surface][s]
- Glazed [Ceramic] Tile
- Glazed Porcelain
- Laminate[s]
- Laminated Surface[s]
- Linoleum
- Plastic
- Plastic Laminate
- Sealed Fiberglass
- Stainless Steel

For all other surfaces test on a small area before use

FSC 35K Reference Sheet**KEEP OUT OF REACH OF CHILDREN****DANGER**

See bottle label for precautionary statements, first aid and storage and disposal information.

Detergent-Disinfectant / Bactericide / Virucide* / Deodorizer / Fungicide / Mildewcide
Hospitals – Medical Environment Disinfectant – Hospitality – Hotels – Nursing Homes – Institutions –
Schools – Restaurants

FOR INDUSTRIAL AND INSTITUTIONAL USE

This product is a “one step” disinfectant mildewcidal cleaner, bactericide and virucide designed for general cleaning and disinfecting of hard, non-porous environmental surfaces. This product is recommended for daily use for disinfecting and cleaning washable hard non-porous environmental surfaces including: bathrooms, shower rooms and spas, shower stalls, tubs, tiles, shower doors, shower curtains, restroom fixtures, urinals, restroom floors, bathroom fixtures, sinks, exterior surfaces of toilets, non-food contact surfaces of coolers, glazed tile, linoleum, plastic (such as polyethylene, polypropylene, polyvinylchloride), chrome, glazed porcelain, stainless steel, glass, and walls. This product is not recommended for use on marble. This product is not for use on food contact surfaces. **Areas of Use:** Hospitals, nursing homes, other healthcare facilities, schools and colleges, veterinary clinics and animal life science laboratories, industrial facilities, beverages and food processing plants, restaurants, hotels, motels, office buildings, recreational facilities, retail and wholesale establishments, animal care and rearing facilities, cruise ships, casinos, correctional facilities, athletic facilities, health clubs.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product concentrate must be dispensed through a closed loop system.

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.

DISINFECTION: For hospital disinfection and cleaning of hard non-porous surfaces according to the AOAC Germicidal Spray Test method in 400 ppm hard water, in the presence of 5% blood serum and 0.005% soap residue. Apply Scrub Free Bathroom Cleaner & Disinfectant with a coarse sprayer or pump-

up sprayer to hard non-porous surfaces only, thoroughly wetting surfaces. All surfaces must remain wet for 5 minutes.

PREPARATION OF USE SOLUTION:

For use as a Daily Cleaner or Daily Restroom / Shower Cleaner: Dilute at 1:64 (2 oz) – 1:21.3 (6 oz) per gallon of use solution. Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous surfaces only, thoroughly wetting surfaces with a sprayer or pump-up sprayer. Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

For use as a Daily Disinfectant / Cleaner or Daily Restroom / Shower Disinfectant / Cleaner: Dilute at 1:32 (4 oz) – 1:21.3 (6 oz) per gallon of use solution. Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous surfaces only, thoroughly wetting surfaces with a sprayer or pump-up sprayer. All surfaces must remain wet for 5 minutes. Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

For use as a Heavy Duty Disinfectant / Cleaner or Heavy Duty Restroom / Shower Disinfectant / Cleaner: Dilute at 1:21.3 (6 oz) per gallon of water. Pre-clean heavily soiled areas. Apply Use Solution to hard, non-porous surfaces only, thoroughly wetting surfaces with a sprayer or pump-up sprayer. All surfaces must remain wet for 5 minutes. Wipe surfaces with damp cloth or sponge. Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

Toilet Bowl Cleaning and Disinfection: Clean toilets by applying (4 oz.) - (6 oz.) of product per 1 gallon of use solution to all outer toilet surfaces, around the bowl, and up under the rim. Stubborn stains may require brushing. To disinfect the outer toilet surfaces, apply (4 oz.) - (6 oz.) of product per 1 gallon of use solution to the surface, thoroughly wetting surfaces with a pump-up sprayer. All surfaces must remain wet for 5 minutes. Wipe outer toilet surfaces with a damp cloth or sponge.

BACTERICIDAL in 5 minutes at 1:32 dilution, 4 oz/gal – 1:21.3 dilution, 6 oz/gal diluted in 400 ppm hard water against the following pathogenic bacteria according to the AOAC Germicidal Spray Test modified in the presence of 5% blood serum and 0.005% soap residue (sodium stearate). Apply Use Solution by coarse spray using a (sprayer) (pump sprayer) (pump-up sprayer) 6 – 8 inches from surface.

Pseudomonas aeruginosa (ATCC 15442)

Staphylococcus aureus (ATCC 6538)

Salmonella enterica (ATCC 10708)

Proteus vulgaris (NCTC 4635)

Serratia marcescens (ATCC 14756)

Streptococcus pyogenes (ATCC 19615)

Antibiotic-Resistant Bacteria:

Escherichia coli O157:H7 (ATCC 43895)¹

Staphylococcus aureus (CA-MRSA) (ATCC BAA-1683)

Staphylococcus aureus (MRSA) (ATCC 33592)¹

¹ for bactericidal activity against *Escherichia coli* O157:H7 and *Staphylococcus aureus* (MRSA) product must be diluted at 6 oz/gal.

For use as a Virucide*: Dilute at 1:32 dilution, 4 oz - 1:21.3 dilution, 6 oz per gallon of use solution. Pre-clean heavily soiled areas. Apply Use Solution by coarse spray using a pump-up sprayer to hard, non-porous surfaces only, thoroughly wetting surfaces. All surfaces must remain wet for 5 minutes, unless otherwise directed. Rinse surface with potable water. Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

***VIRUCIDAL** in 5 minutes at 1:32 dilution (4 oz/gal) - 1:21.3 dilution (6 oz/gal) diluted in 400 ppm hard water against the following viruses according to the Virucidal Qualification Test modified in the presence of 5% blood serum and 0.005% sodium stearate. Apply Use Solution by coarse spray using a pump-up sprayer 6 – 8 inches from surface.

**Hepatitis B Virus*

**Hepatitis C Virus*

**Herpes Simplex Virus Type 1* (ATCC VR-733)

**Herpes Simplex Virus Type 2* (ATCC VR-734)

**Human Coronavirus* (ATCC VR-740)

**Influenza A Virus H1N1*

**Influenza B Virus* (ATCC VR-823)

**Murine Norovirus* (Strain MNV-1.CW1)

**Respiratory Syncytial Virus* (RSV) (ATCC VR-26)

**Human Immunodeficiency Virus Type 1* (Strain HTLV-111B) (HIV-1)

For use as a Virucide for Norovirus (Feline Calicivirus) (ATCC VR-782)*: Dilute at 1:21.3 dilution, 6 oz per gallon of use solution. Pre-Clean heavily soiled areas. Apply Use Solution by coarse spray using a (sprayer) (pump sprayer) (pump-up sprayer) to hard, non-porous surfaces only, thoroughly wetting surfaces. All surfaces must remain wet for 5 minutes, unless otherwise directed. (Rinse surfaces with damp cloth or sponge). (Rinse surface with potable water). Prepare a fresh solution daily or sooner if solution becomes diluted or soiled.

***Norovirus (Feline Calicivirus) (ATCC VR-782) VIRUCIDAL** in 5 minutes at 1:21.3 dilution (6 oz/gal diluted in 400 ppm hard water against the following viruses according to the Virucidal Qualification Test modified in the presence of 5% blood serum and 0.005% soap residue (sodium stearate). Apply Use Solution by coarse spray using a (sprayer) (pump sprayer) (pump-up sprayer) 6 – 8 inches from surface.

***KILLS HIV-1 (AIDS VIRUS) ON PRE-CLEANED 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 the transmission of Human Immunodeficiency Virus Type 1 associated with AIDS.

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

Personal Protection: Clean-up must always be done wearing disposable protective gloves, gowns, masks and eye protection.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this product.

Contact Time: Allow surface to remain wet for 5 minutes.

Disposal of Infectious Material: Blood, body fluids, cleaning materials and other clothing must be autoclaved and disposed of according to local regulations for infectious waste disposal.

For use as a Fungicide: This product is effective against *Trichophyton interdigitale* (Athlete's Foot fungus) (ATCC 9533) and *Candida albicans* (ATCC 10231) when used at 1:32 dilution, 4 oz - 1:21.3 dilution, 6 oz per gallon of use solution. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

For use as a Mildewcide: This product is effective against *Aspergillus niger* (ATCC 6275) when diluted at 1:32 dilution, 4 oz - 1:21.3 dilution, 6 oz per gallon of use solution at a contact time of 5 minutes in the presence of 5% organic soil load. Apply as directed in the Disinfection / Cleaning / Deodorizing directions for use.

NON-FOOD CONTACT SURFACE SANITIZING: Dilute at 1:32 dilution, 4 oz - 1:21.3 dilution, 6 oz per gallon of use solution. This product is an effective sanitizer against *Enterobacter aerogenes* (ATCC 13048), and *Staphylococcus aureus* (ATCC 6538) on hard, non-porous environmental surfaces only. Apply product by coarse spray using a sprayer, pump-up sprayer, wet cloth, mop, scrubber, or by soaking. Treated surfaces must remain wet for 60 seconds. Rinse and dry with sponge, squeegee, mop or cloth or allow to air dry. Prepare a fresh solution at least daily or sooner if solution becomes diluted or soiled.

VETERINARY OFFICES: Remove all animals and feeds from premises, animal transportation vehicles, crates, etc. Remove all litter, droppings and manure from floors, walls and surfaces of facilities occupied or traversed by animals. Empty all feeding and watering appliances. Dilute at 1:32, 4 oz - 1:21.3, 6 oz per gallon of water. Saturate the surfaces for a period of 5 minutes. Wipe or allow to air dry. Saturate all hard, non-porous animal handling and restraining equipment as well as forks, shovels, and scrapers used to remove litter and manure. Rinse all surfaces that come in contact with food, including equipment used for feeding and watering, with potable water before reuse. Ventilate buildings and other closed spaces. Do not house animals or employ equipment until treatment has been absorbed, set or dried.

DISINFECTION AND DEODORIZING OF ANIMAL HOUSING FACILITIES (BARN, 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. Dilute at 1:32, 4 oz - 1:21.3, 6 oz per gallon of water. Saturate all hard, non-porous animal restraining equipment, as well as forks, shovels, and scrapers used for removing litter and manure for a period of 5 minutes. 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.)

(Note to reviewer: The following are optional graphics that will be used to illustrate possible use sites.)



SECONDARY CONTAINER LABEL(Note to reviewer: This secondary container label will be used only when the product is diluted 4 – 6 oz per gallon of water.)

FSC 35K

(Concentrate Ingredient Statement)

Active Ingredients:

| | |
|---|---------------|
| Alkyl (C14, 50%; C12, 40%; C16, 10%) Dimethyl benzyl ammonium chloride..... | 1.63% |
| Octyl decyl dimethyl ammonium chloride..... | 1.22% |
| Didecyl dimethyl ammonium chloride..... | 0.74% |
| Dioctyl dimethyl ammonium chloride..... | 0.49% |
| Other Ingredients | <u>95.92%</u> |
| Total: | 100.00% |

The product in this container must be diluted at the use rate of 4 – 6 oz per gallon of water as directed on the concentrate product label.

Diluted product in this container is _____ oz. per gallon water.

Use solution prepared by the end user

NOT FOR SALE OR DISTRIBUTION

KEEP OUT OF REACH OF CHILDREN

DO NOT DRINK

USE SOLUTION - PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Harmful if inhaled, swallowed, or absorbed through the skin. Avoid contact with skin, eyes, or clothing. Avoid breathing vapor. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID

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

If on skin: 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 by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-328-0026
OUTSIDE NORTH AMERICA, CALL 1-651-222-5352**

Follow the directions for use on the concentrate label when applying this product.

EPA Reg. No. 1677-256

Emerging Viral Pathogens

“This product qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.”

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large, Non-Enveloped Viruses

| <i>For an emerging viral pathogen that is a/an...</i> | <i>...follow the directions for use for the following organisms on the label</i> |
|---|--|
| Enveloped virus | Feline Calicivirus [surrogate for Norovirus] |
| Large, Non-Enveloped virus | Feline Calicivirus [surrogate for Norovirus] |

Acceptable claim language:

FSC 35K has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, FSC 35K can be used against [name of emerging virus] when used in accordance with the directions for use against Feline Calicivirus [surrogate for Norovirus] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name of emerging virus]. FSC 35K kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Feline Calicivirus [surrogate for Norovirus] on hard, non-porous surfaces. Refer to

the [CDC or OIE] website at [website address] for additional information.