



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

August 13, 2018

Bridget Middleton  
Ecolab Inc.  
1 Ecolab Place  
St. Paul, MN 55102

Subject: PRIA Label Amendment – Revised to Include *C. difficile* Spores on Contaminated Laundry, Updated Marketing Language, and Revised Precautionary Statement Per the Label Review Manual  
Product Name: AdvaCare 120 Sanitizer/Sour  
EPA Registration Number: 1677-193  
Application Date: March 23, 2018  
Decision Number: 539638

Dear Ms. Middleton:

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.

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

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with FIFRA section 6. If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at [northern.terria@epa.gov](mailto:northern.terria@epa.gov).

Enclosure: Accepted label

Sincerely,

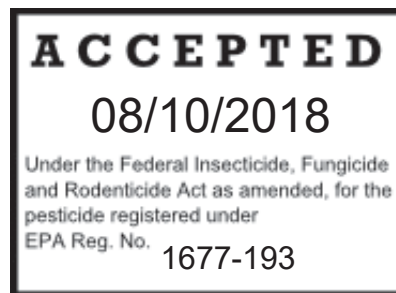
A handwritten signature in blue ink, appearing to read "John Hebert", with a large, stylized flourish at the end.

John Hebert, Chief  
Regulatory Management Branch 1  
Antimicrobials Division (7510P)  
Office of Pesticide Programs

# AdvaCare 120 Sanitizer/Sour

(Note to reviewer – any of the following descriptors may appear on the label)

Laundry Sanitizer  
Laundry Bleach  
Laundry Sour  
Laundry Sanitizer/Sour  
Laundry Oxidizer  
Laundry Disinfectant



## Active Ingredients:

Peroxyacetic acid ..... 15.2%  
Hydrogen peroxide ..... 11.2%

**Inert Ingredients** ..... 73.6%

**Total** ..... 100.0%

## KEEP OUT OF REACH OF CHILDREN DANGER

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

## PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**CORROSIVE:** Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if swallowed. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing, and rubber gloves when handling. 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. Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N, R, or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N, R, or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters.

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

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the 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**

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.

**PHYSICAL AND CHEMICAL HAZARDS:**

Strong oxidizing agent. Corrosive. Do not use in concentrate foam. Mix only with water according to the label instructions. Never bring concentrate in contact with other sanitizers, cleaners or organic substances.

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

(Note to reviewer: Items in brackets [AAA] or parentheses (AAA) are optional and may/may not be included on final label)

(AdvaCare 120 Sanitizer/Sour is a concentrate formulation designed for use in commercial, institutional and industrial laundry operations.)

**DIRECTIONS FOR USE**

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

**To Disinfect and Bleach**

Using the appropriate Ecolab dispenser, inject AdvaCare 120 Sanitizer/Sour into the bleach or rinse step. AdvaCare 120 Sanitizer/Sour is effective in water up to 500 ppm of water hardness (up to 29 grains per gallon). Use AdvaCare 120 Sanitizer/Sour at a rate of 4 to 12 fluid ounces per maximum 60 gallons of water to disinfect a maximum of 100 pounds dry laundry (cwt) according to the use directions below. (119 to 355 mL per maximum 227 L of water to disinfect a maximum of 45 kg dry laundry). Treat the laundry for a minimum of 5 minutes at 140°F to 160°F (60°C to 71°C). Softener can subsequently be added after the 5 minute disinfecting step. Following the disinfection step, the laundry may be rinsed with water that may include starch, softener, odor neutralizer, fragrance, soil release agent, sour and/or fluid repellent. For further bleaching action, an additional dose of product up to 16 fl. oz./cwt may be added in the bleach or rinse step at a temperature of 90°F to 160°F (32°C to 71°C). Use level, time and temperature will vary depending on stain level, fabric type and load weight. (See list of organisms for required rate of use and heat requirements)

When added as a disinfecting agent at a rate of 4 fluid ounces per 100 pounds of dry laundry at 140°F, the formulation provides disinfection against:

*Staphylococcus aureus* (ATCC 6538)  
*Klebsiella pneumoniae* (ATCC 4352)  
*Pseudomonas aeruginosa* (ATCC 15442)  
Methicillin-resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)  
*Staphylococcus aureus* (CA-MRSA) (ATCC BAA-1556)  
*Acinetobacter baumannii* (ATCC 19606)  
*Listeria monocytogenes* (ATCC 49594)  
*Escherichia coli* O157:H7 (ATCC 43895)  
*Salmonella enterica* (ATCC 10708)  
HIV-1 (AIDS Virus)

When added as a disinfecting agent at a rate of 8 fluid ounces per 100 pounds of dry laundry at 160°F, the formulation provides disinfection against:

*Enterococcus faecalis*-VRE (ATCC 51299)

Carbapenem-resistant *Klebsiella pneumoniae* (ATCC BAA-1705)

When added as a disinfecting agent at a rate of 12 fluid ounces per 100 pounds of dry laundry at 160°F, the formulation provides disinfection against:

*Clostridium difficile* (ATCC 43598)

Used as directed, treatment will kill spores of *Clostridium difficile* on contaminated [healthcare] laundry and in the laundry wash water.

### **SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 ON SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:**

**Personal Protection:** Clean-up must always be done wearing 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.

### **To Sanitize and Bleach**

Using the appropriate Ecolab dispenser, inject AdvaCare 120 Sanitizer/Sour into the bleach rinse step. AdvaCare 120 Sanitizer/Sour is effective in water up to 500 ppm of water hardness (up to 29 grains per gallon). Use AdvaCare 120 Sanitizer/Sour at a rate of 3 fluid ounces per maximum 60 gallons of water to sanitize a maximum of 100 pounds dry laundry (89 mL per maximum 227 L of rinse water to sanitize a maximum of 45 kg dry laundry). Treat the laundry for a minimum of 5 minutes at 90°F to 160°F (32°C to 71°C). Softener can subsequently be added after the 5 minute sanitizing step. Following the sanitizing step, the laundry may be rinsed with water that may include starch, softener, odor neutralizer, fragrance, soil release agent, sour and/or fluid repellent. For further bleaching action, an additional dose of product up to 17 fl oz/cwt may be added in the bleach or rinse step at a temperature of 90°F to 160°F (32°C to 71°C). Use level, time and temperature will vary depending on stain level, fabric type and load weight.

When added as a sanitizing agent at the rate of 3 fluid ounces per 100 pounds of dry laundry, this formulation provides sanitization against:

*Staphylococcus aureus* (ATCC 6538)

*Klebsiella pneumoniae* (ATCC 4352)

*Pseudomonas aeruginosa* (ATCC 15442)

Methicillin-resistant *Staphylococcus aureus* (MRSA) (ATCC 33592)

### **To Bleach Only**

AdvaCare 120 Sanitizer/Sour can be used for bleaching of linen. To bleach, dose up to 20 fl. oz./cwt of AdvaCare 120 Sanitizer/Sour in the appropriate bleaching step at a temperature of 90°F to 160 °F (32°C to 71 °C). Use levels, time and temperature will vary depending on the type of soil, fabric, and load. For best results, please consult your Ecolab Laundry Specialist. Following the bleach/sanitizing step, the laundry may be rinsed with water that may include sour, starch, softener, odor neutralizer, fragrance, soil release agents, and/or fluid repellent.

FOR COMMERCIAL OR INSTITUTIONAL USE  
STRONG OXIDIZING AGENT  
DO NOT MIX WITH ANYTHING BUT WATER  
VENTED CONTAINER: STORE UPRIGHT IN A COOL PLACE, TIGHTLY CAPPED.

U.S. Patent # 6,262,013.

**STORAGE & DISPOSAL**

DO NOT CONTAMINATE WATER, FOOD OR FEED BY STORAGE OR DISPOSAL

**PESTICIDE STORAGE:** Product must be kept cool and in vented container to avoid any explosion hazard.

**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 HANDLING AND DISPOSAL:**

(Non-refillable sealed container) Do not reuse or refill this container. Wrap empty container and place in trash.

(For containers 5 gallons or less.) Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Fill container  $\frac{1}{4}$  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  $\frac{1}{4}$  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.

(Totes) Verify that the tote is empty. Do not rinse or clean. Seal tote and contact Ecolab for return.

EPA Reg No. 1677-193

EPA Est. 1677-MN-1 (P), 60156-IL-1 (SI), 5389-NC-1 (G),  
1677-CA-2(R), 1677-TX-1(D), 1677-IL-2 (J), 303-IN-1 (L),  
1677-GA-1 (M), 1677-CA-1(S), 1677-WV-1(V), 58046-TX-2 (X)  
Superscript refers to first letter of date code

**Net Contents:**

4 U.S. Gals. (15.1 liters)  
12 U.S. Gals (45.3 liters)  
50 U.S. Gals. (189 liters)  
300 U.S. Gals (1136 liters)

Ecolab Inc.

1 Ecolab Place

St. Paul, MN 55102

(Made in United States of America) (Made in USA)

This product may be patented | Ce produit peut être breveté | Este producto puede ser patentado:  
[www.ecolab.com/patents](http://www.ecolab.com/patents)

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(Si no puede leer en inglés, pregunte a su supervisor sobre las instrucciones de uso apropiadas antes de trabajar con este producto.)



## AdvaCare 120 Sanitizer/Sour Marketing Claims

- Kills [at 99.9999%] [*Clostridium difficile*] [*C. diff*] [spores] [in 5 minutes] [in the laundry] [on contaminated [healthcare] laundry (linen)] [on linen] [in the laundry wash water] [without bleach] [on both the [healthcare] [laundry] [linen] [and in the [wash] water (during the wash process)] [to help reduce cross-contamination of [*Clostridium difficile*] [*C. diff*] [spores] [from contaminated laundry (linen)] to other laundry (linen)]
- Disinfects [at 99.9999%] [*Clostridium difficile*] [*C. diff*] [spores] [in the laundering process] [without bleach] [on both contaminated [healthcare] [laundry] [linen] and in the [wash] water] [on [laundry] [linen] [patient gowns] [surgical gowns] [[surgical] [operating room] [OR] [barrier] textiles] [(barrier) gowns] [blankets] [bedding] [coats] [scrubs] [suits] [personal protective [wear] [equipment]] [PPE] [surgical wraps] [surgical drapes] [drapes] [and covers] [cubical curtains]] [on [garments] [workwear] [uniforms] [food processing garments] [HACCP garments] [personal protective wear] [PPE]]
- [Effectively] kills many bacteria, [[and] HIV], [and] [*Clostridium difficile*] [*C. diff*] [spores] [in 5 minutes [min]] [in the laundering process] [without bleach] [including [CRE [KPC] [VRE] [MRSA] [CA-MRSA] [*Clostridium difficile*] [*C. diff*] [spores]]] [as listed on the label]
- Kills [at 99.9999%] [(the spore-former) *Clostridium difficile*] [*C. diff*] [spores] [in the laundry process] [without bleach]
- Attacks and kills [at 99.9999%] [*Clostridium difficile*] [*C. diff*] [spores] [on [contaminated] [healthcare] linen] [without bleach]
- [Designed] [Formulated] [[provides] peace of mind] for killing [*Clostridium difficile*] [*C. diff*] [spores] [in 5 minutes [min]] [on [contaminated] [healthcare] [linen] [textiles]] [without bleach] [by utilizing an EPA approved [method] [process] for killing spores in a laundering process]
- Effective against [*Clostridium difficile*] [*C. diff*] [spores] [at 99.9999%] [which can be present on [contaminated] healthcare [laundry] [linens]]
- Disinfects [at 99.9999%] against [*Clostridium difficile*] [*C. diff*] [spores] [when used at the proper concentration, time, and temperature requirements in the [laundry] wash process]
- [Disinfects] [Kills] [at 99.9999%] [*Clostridium difficile*] [*C. diff*] [spores] in the laundering process [and in the laundry wash water]
- Effective as a [*Clostridium difficile*] [*C. diff*] [spore] disinfectant for use on [[contaminated] healthcare [textiles] [linens]] [including [contaminated] [[ambulatory] [acute] care center linens] [hospital] [long term care facility] [nursing home] [retail healthcare] [[outpatient] surgical centers] [and] [other healthcare setting linens]
- Kills [99.9999% of] [*Clostridium difficile*] [*C. diff*] [spores] in 5 minutes in the laundering process
- Effective in 5 minutes in the laundering process for microorganisms listed on the label
- [Effectively] kills many bacteria, [[and] HIV] and [*Clostridium difficile*] [*C. diff*] spores [including [CRE [KPC] [VRE] [MRSA] [CA-MRSA]]
- Tough on bacteria, [HIV] and spores but safe on [sensitive] [delicate] textiles [such as [colored fabrics], [chlorine-sensitive] [fabrics] [textiles], non-bleachable [fabrics] [textiles]] [and designed for regular laundering use]
- A comprehensive [EPA] registered laundry [oxidizer] [disinfectant] concentrate available for [contaminated] [healthcare] [and] [food processing] textiles



- Effective at disinfecting [contaminated linen] at lower wash temperatures and less time [than the CDC and HICPAC 2003 recommendation (guideline) for processing healthcare linens]
- A(n) [chemical] antimicrobial intervention in the laundering wash process
- [Kills] [and disinfects] [at 99.9999%] microorganisms of concern [in healthcare] [in food processing] [in food service] [in hospitality]
- All of the bacteria on the label were killed [disinfected] [at 99.9999%] [with a starting level of bacteria above 6 logs]
- Gentle on the most [sensitive] [delicate] fabrics [including [colored fabrics], [chlorine-sensitive] [fabrics] [textiles], non-bleachable [fabrics] [textiles]]
- Effectively kills microorganisms at low(er) wash temperatures
- Both an oxidizer and antimicrobial [and provides excellent whitening]
- Kills [disinfects] [at 99.9999%] [super bugs] [such as] Carbapenem-resistant *Enterobacteriaceae* (CRE), and Vancomycin-resistant *Enterococcus faecalis* (VRE) bacteria [in 5 minutes] [in the laundry process] [without bleach] [for [contaminated] healthcare linen]
- Kills [at 99.9999%] antibiotic resistant bacteria [or super bugs] of great concern to healthcare facilities [VRE] [and][CRE] [MRSA][KPC]
- Kills [at 99.9999%] [super bugs] [such as] [Carbapenem-resistant *Enterobacteriaceae*] [CRE's], Including [*Klebsiella pneumoniae*- Carbapenem-resistant (KPC)]
- Kills with oxidizing power to help reduce the spread of drug resistant [[micro]organisms] [strains] [and [*Clostridium difficile*] [*C. diff*] [spores]]
- Two in one oxidizing and disinfecting [solution] [disinfectant] [agent] [utilized [for use] in the laundering process]
- Effective against Multidrug Resistant Organisms [MDROs] [super bugs] [including [VRE] [KPC] [CRE] [MRSA]] [, and [*Clostridium difficile*] [*C. diff*] [spores]]
- [Effective against] [kills] [at 99.9999%] super bugs [including [VRE] [KPC] [CRE] [and] [MRSA]]
- Kills multiple strains of drug resistant [super bugs of] *Staphylococcus aureus*, including Methicillin-resistant *Staphylococcus aureus* (MRSA), and Methicillin-resistant *Staphylococcus aureus*- Community Acquired (CA-MRSA)
- Kills [disinfects] *Klebsiella pneumoniae* (KPC), a Carbapenem-resistant *Enterobacteriaceae* (CRE), [and] *Enterococcus faecalis* (VRE) [, and [*Clostridium difficile*] [*C. diff*] [spores]]
- Kills microorganisms of concern [in food processing] [in the food processing market] [related to food borne illness], including [*Listeria monocytogenes* (Listeria)] [*Salmonella enterica*] [Salmonella] [*Staphylococcus aureus*] [Staph] [*Escherichia coli* O157:H7] [E. Coli] [in 5 minutes] [in the laundry process] [for food processing textiles][for HACCP textiles][for Personal Protective Equipment (PPE) [and [contaminated] textiles]
- Kills [disinfects] the bloodborne pathogen HIV [in 5 minutes] [without bleach] [for contaminated] [healthcare linen]
- Kills [MRSA] [KPC, a CRE bacteria] [MRSA] [CA-MRSA] [HIV] in 5 minutes [in the wash process]
- Contains no [bleach] [or] [Sodium Hypochlorite]
- Clean, fresh smell [with no bleach fumes]
- Bleach free

- Does not contain bleach
- Safe for colored [and sensitive] fabrics [including [colored fabrics], [chlorine-sensitive] [fabrics] [textiles], non-bleachable [fabrics] [textiles]]
- Closed-loop, easy and convenient [to use] [for [contaminated] healthcare linen] [for [soiled] [contaminated] food processing garments] [for sensitive fabrics] [including [colored fabrics], [chlorine-sensitive] [fabrics] [textiles], non-bleachable [fabrics] [textiles]] [for colored fabrics] [for [soiled] [contaminated] food and beverage linens] [for [soiled] [contaminated] hospitality [linens] [textiles] ]
- Aids in the reduction of cross-contamination in water in the wash process [by killing microorganisms in the wash water [and on the linen [textile] itself
- Kills [or] [disinfects] microorganisms [of concern] [on the label] in the laundry wash water
- For use in all commercial [and on premise] laundry facilities
- Safe for use on a variety of textiles [including] [healthcare [contaminated] linens [and scrubs] [and surgical attire]] [hospital linens] [industrial [soiled] [textiles] [garments]] [HACCP [soiled] [contaminated] garments] [Personal Protective Equipment [PPE] [soiled] [contaminated] [garments]] [clean room [soiled] garments]
- Kills [disinfects] microorganisms of concern on [including] [healthcare [contaminated] linens [and scrubs] [and surgical attire]] [hospital linens] [industrial [soiled] [contaminated] textiles] [hospitality [soiled] [contaminated] linens [textiles]] [food processing [soiled] [contaminated] garments] [HACCP [soiled] [contaminated] garments] [Personal Protective Equipment [PPE] [soiled] [contaminated] [garments]] [clean room [soiled] garments]