



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 22, 2020

Rob R. Adams, Jr.
President
Adams Technology Systems LLC
5145 Forest Run Trace, Suite B
Alpharetta GA, 30022

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: Biosenta Antimicrobial 0.5%
EPA Registration Number: 90276-2
Application Date: July 1, 2020
Decision Number: 564473

Dear Mr. Adams:

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 are 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 Poliovirus Type 1 or Hepatitis A Virus 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,



Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

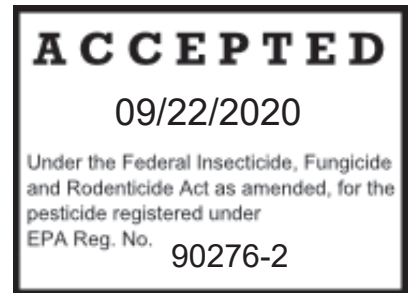
Enclosure: stamped label

Biosenta Antimicrobial 0.5%

[ABN's: (9) Biosano, Biosani, Niagara, True, Galaxy, Overall, Cleaning Force, CleanAway, Clean Genie,
(6) Mold Remove, Mold Take Out, Mold Solution, Mold Fix, Mold Aid, Mold Response]

Germicidal •Disinfects •Deodorizes FULL SPECTRUM DISINFECTANT

- Ready To Use
- Covers 200–400 sq. ft. [alternate coverage permitted as per container size and application method]
- Disinfects counters, bathrooms, walls, floors and other hard, non-porous surfaces
- Money Back Guarantee
- Antimicrobial Mold Eliminator
- Fungicide
- Bactericide
- Virucide
- Destroys [Kills] mold and mold spores on hard, non-porous surfaces



ACTIVE INGREDIENT:	
Sodium Hypochlorite	0.5%
OTHER INGREDIENTS:	99.5%
TOTAL:	100.0%
. Contains no phosphorus	

KEEP OUT OF REACH OF CHILDREN

Manufactured for:
BIOSENTA INC.
18 WYNFORD DRIVE UNIT 704
TORONTO, ONTARIO M3C 3S2
CANADA
Visit us at www.biosenta.com

EPA Reg. No. 90276-2

EPA Est. 20909-CA-001

[Alternate EPA Establishments: May be jet coded or designated in the Lot# or Batch#]

Net Contents: 32 fl. oz. (946 ml) [or alternate sizes]

PHYSICAL AND CHEMICAL HAZARDS

Do not use this product with other chemicals such as ammonia, toilet bowl cleaners, rust removers, or acid, as this releases hazardous gases. APPLY CAREFULLY - This product contains bleach.

[Required for containers greater than 5 gallons]

ENVIRONMENTAL HAZARDS

This product is toxic to fish and aquatics.

[All directions may be written in numbered form or in paragraph form.]

Biosenta Antimicrobial 0.5% *[or other product name]* is a ready-to-use multi-purpose spray with disinfectant activity against the following:

[For reviewer clarity, all efficacy claims have been added to the end of the label.]

It eliminates odors and effectively cleans a wide range of hard, non-porous surfaces such as sealed wood, floors, walls, countertops, sealed tile, sealed stone and sealed concrete. This product may be used in households, commercial, institutional and industrial areas such as; homes, offices, schools, cars, boats, RV's on any hard, non-porous surface.

DIRECTIONS FOR USE

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

Do not dilute **Biosenta Antimicrobial 0.5%** *[or other product name]*. Repeat treatment as needed.

1. Prepare area to be treated by removing any heavy soil from surface.
2. Spray **Biosenta Antimicrobial 0.5%** *[or other product name]* directly onto cleaning surface until visibly wet
3. After 10 minutes, scrub with a brush then wipe down surface to remove residue. For surfaces that come in contact with food, a potable water rinse is required.

STORAGE AND DISPOSAL

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

[For containers 5 gallons or less]

STORAGE: Store this product in a cool dry area, away from direct sunlight and heat to avoid deterioration.

PRODUCT DISPOSAL: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer.

CONTAINER HANDLING: Nonrefillable container. Only refill with this product. Do not reuse this container. Offer for recycling if available or reconditioning if appropriate or place in trash.

[For containers greater than 5 gallons]

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: 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 back and forth several times. Turn the container over onto its other end and tip back and forth several times. Follow Product Disposal instructions for rinsates disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

[Alternate language to be used as appropriate]

Biosenta Customer Assistance 1-855-410-2019

If you have any questions or comments, please call! The team at Biosenta will assist you.

Call toll-free 1-855-410-2019. Satisfaction Guaranteed! :)

[or] At Biosenta we aim for the highest quality and best value products. We are dedicated to ensuring your complete satisfaction with our product. If you are not completely satisfied, please call 1-855-410-2019.

Biosenta Antimicrobial 0.5% *[or other product name]* is a registered trademark of Biosenta Inc.

Manufactured in United States

[Optional Logos and claims]

- Bottle is coded for recycling where HDPE containers are accepted.
- Recyclable Container
- Made in U.S.A.
- Not harmful to septic and waste water treatment systems.
- This bottle is coded for recyclers. Check to see if recycling facilities accept colored HDPE in your area. Recycle where [Recycling] facilities are available.
- Contains no phosphorus -or- phosphates.

*[Efficacy claims]*Bactericidal

Biosenta Antimicrobial 0.5% *[or other product name]* is a disinfectant with bactericidal activity against the following on hard non-porous surfaces for a contact time of 10 minutes:

- Staphylococcus aureus (ATCC 6538)*
- Salmonella enterica (ATCC 10708)*
- Listeria monocytogenes (ATCC 43257)*
- Escherichia coli (ATCC 25922)*

Fungicidal

Biosenta Antimicrobial 0.5% *[or other product name]* is a disinfectant with fungicidal activity against the following on hard, non-porous surfaces for a contact time of 10 minutes:

- Trichophyton interdigitale (ATCC 9533)*

Virucidal

Biosenta Antimicrobial 0.5% *[or other product name]* is a disinfectant with virucidal activity against the following microorganisms in the presence of a 5% organic soil load for a contact time of 10 minutes:

- Polio virus Type 1 (ATCC VR-1562)*
- Swine Influenza A virus (H1N1) (ATCC VR-333)*
- Herpes Simplex virus Type 1 (ATCC VR-733)*
- Influenza A virus (H1N1) (2009) (CDC#2009712192)*
- Hepatitis A virus (HM-175, APPTEC LAB SERVICES)*
- Respiratory Syncytial virus (ATCC VR-26)*

<<Emerging Viral Pathogens Claim – Hard, non-porous surfaces>>

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 category[ies]:

- 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	Poliovirus Type 1 Hepatitis A Virus
Large, non-enveloped virus	Poliovirus Type 1 Hepatitis A Virus

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus Type 1 or Hepatitis A Virus 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]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against Poliovirus Type 1 or Hepatitis A Virus on hard, non-porous surfaces]. Refer to the [CDC or OIE] website at [website address] for additional information.”