



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 12, 2020

Dr. Connie B. Welch-DuJardin
Authorized Agent
Envyss, LLC
P.O. Box 907
Blue Ridge, GA 30513

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: BioBuster
EPA Registration Number: 92589-1
Application Date: May 6, 2020
Decision Number: 562618

Dear Dr. Welch-DuJardin:

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, 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 Canine Parvovirus 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

All text in brackets [] is optional and may or may not be included on a final label.

BioBuster

Broad Spectrum Disinfectant and Virucide
Deodorizer

Alternate Brand Names

BioBuster Disinfectant and Virucide

BioBuster Broad Spectrum Disinfectant

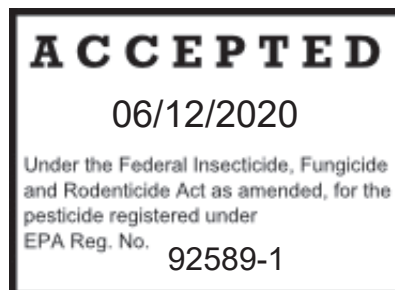
BioBuster VC Broad Spectrum Disinfectant for Veterinary Clinic Use

BioBuster VC Disinfectant and Virucide for Veterinary Clinic Use

BioBuster HD Disinfectant and Virucide for Farm Use

BioBuster Greenhouse Disinfectant and Virucide

BioBuster FP Broad Spectrum Hard Non-porous Disinfectant for Animal Processing Facilities



[BROAD SPECTRUM DISINFECTANT for Hard Non-Porous Surfaces,] [CLEANER,]
[VIRUCIDE,] [& ALGAECIDE]. [Poultry Hatchery Disinfectant] [Farm Premise Disinfectant]
[Veterinary and Animal Hospital Disinfectant] [For Poultry, Swine and Livestock Premises] [For
Veterinary, Laboratory Animal, Kennel and Animal Breeder Facilities] [Effective in 400ppm
Hard Water as CaCO₃] [Disinfects in 5% Organic Soil Load] [For Greenhouse Facilities and
Equipment] [For use in Horticulture] [Processing and Slaughter Plant Disinfectant] [For
Aquaculture Facilities] [Routine Cleaning in Commercial and Industrial Facilities]

For Use in Cleaning or Disinfecting Industrial, Commercial, Animal and Agricultural Facilities.
BioBuster can also be used as a deodorizer.

Effective against:

Virus

Bacteria

ACTIVE INGREDIENTS:

Potassium peroxymonosulfate	21.40%
Sodium Chloride	1.50%
OTHER INGREDIENTS	77.10%
TOTAL	100.00%

KEEP OUT OF REACH OF CHILDREN

DANGER/PELIGRO

EPA Reg. No. 92589-1

EPA Est. No.

Batch No:

Expiry Date:

Net Contents:

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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 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for further 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 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 INFORMATION	
[For 24-hour emergency information on this product, call the poison control center 1-800-222-1222.] 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.	

Manufactured for:
EnVyss, LLC
178 Rowland Pointe
Morganton, GA 30560

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BioBuster is effective against:

BACTERIA:

[*Aeromonas hydrophila* (ATCC19570)]
[*Campylobacter jejuni* (ATCC 33560)]
[*Escherichia coli*O157:H7 (ATCC 35150)]
[*Haemophilus somnus* (ATCC 700026)]
[*Mycoplasma gallisepticum* (ATCC15302)]
[*Pectobacterium carotovorum* (ATCC15713)]
[*Pseudomonas aeruginosa* (ATCC15442)]
[*Salmonella enterica* (ATCC10708)]
[*Staphylococcus aureus* (ATCC6538)]
[*Streptococcus suis* (ATCC 43765)]
[*Bordetella avium* ATCC35086]
[*Bordetella bronchioseptica* (ATCC10580)]
[*Listeria monocytogenes* (ATCC984)]
[*Streptococcus pneumoniae* (ATCC 33400)]
[*Xanthomonas campestris* (ATCC 11058)]

VIRUSES:

Avian Influenza Virus (H5N1) (Strain VNH5N1-PR8/CDC-RG)
Bovine Adenovirus Type 4
Bovine Polyoma Virus
Bovine Pseudocowpox Virus
Bovine Viral Diarrhea Virus (Strain : NADL (America Bioresearch laboratories)
Calf Rotavirus (no hard water –dilute with deionized water)
Canine Adenovirus (Canine Hepatitis)
Canine Corona Virus
Canine Parainfluenza Virus
Canine Parvovirus(Strain: Cornell-780916-80, ATCC VR-2017)
Chicken Anemia Virus
Coital Exanthema Virus
Distemper Virus
Duck Adenovirus (no hard water –dilute with deionized water)
Duck Enteritis Virus
Egg Drop Syndrome Virus
Equine Herpes Virus (Type3)
Equine Influenza Virus (Type A)
Equine papilloma virus
Feline Herpes Virus
Feline Infectious Peritonitis Virus (Strain FIPV-1146, P100 ATCC VR-2202)
Feline Panleukopenia Virus

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Hog Cholera Virus
Infectious Laryngotracheitis Virus (Strain LT-IVAX)
Infectious Pancreatic Necrosis
Infectious Salmon Anemia Virus
Marek's Disease
Mouse Parvovirus
Pigeon Adenovirus (Strain IDA4: RVB-0146)
Porcine Parvovirus

Snakehead Rhabdovirus
Swine Influenza Virus
Swine Vesicular Stomatitis Virus
Turkey Herpes Virus (no hard water- dilute with deionized water)
Vesicular Stomatitis Virus

[PLANT PATHOGENS]

[Botrytis cinera]

[Fusarium oxysporum]

[Penicillium oxalicum]

[Pythium aphanidermatium]

[Rhizoctonia solani]

[Sclerotinia sclerotiorum]

PRECAUTIONARY STATEMENTS:

Hazards to human and domestic animals.

DANGER. Powder is corrosive in concentrated form.

Causes irreversible eye damage or skin burns. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Wear protective eyewear, protective clothing and rubber gloves. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Corrosive statement refers to powder only and not to the product in use dilution.

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 local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

[BioBuster Virucide and Disinfectant is a complete, chemically balanced disinfectant formulated to be environmentally friendly. BioBuster Virucide and Disinfectant provides broad spectrum efficacy, killing gram positive and gram negative bacteria, virus, mycoplasma [and inhibiting

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the formation of slime and algae and associated slime forming bacteria] in industrial, animal and agricultural facilities and for use in greenhouses, horticulture and aquaculture on hard non-porous surfaces.

DIRECTIONS FOR USE

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

GENERAL INSTRUCTIONS — FARM PREMISES, ANIMAL HOUSING BUILDINGS AND FARM EQUIPMENT

1. Remove all animals and feed from premises, vehicles and enclosures. Remove all litter and manure from floors, walls and surfaces of barns, pens, stalls, chutes and other facilities and fixtures occupied or traversed by animals. Empty all troughs, racks, and other feeding and watering appliances.
2. Thoroughly clean all surfaces with detergent and rinse with water.
3. Saturate all surfaces with the appropriate disinfection solution. Surfaces must remain wet for 10 minutes.
4. Immerse all animal handling equipment and forks, shovels, and scrapers used for removing litter and manure in the appropriate disinfection solution for 10 minutes. Allow to air dry.
5. Ventilate buildings and other closed spaces. Do not house animals or livestock or use equipment until the disinfection solution has been absorbed, set, or dried.
6. Thoroughly scrub treated feed racks, troughs, automatic feeders, and waterers with detergent and rinse with potable water before reuse.

BIOBUSTER MIXING INSTRUCTIONS:

To mix the appropriate use-diluted solution of BioBuster, first identify the percent solution desired. Second, fill a clean container with the volume of water for the desired percent solution and then add the associated quantity of powder (using the provided scoop) found in the following table. One scoop (1.3 ounces of powder) added to one gallon of water will yield a 1% solution.

Quantity of Water	0.5% Solution	1% Solution	2% Solution
1 Quart	0.15 ounces	0.325 ounces	0.7 ounces
1 Gallon	0.65 ounces	1.3 ounces	2.7 ounces
10 Gallons	6.7 ounces	13.4 ounces	26.7 ounces
50 Gallons	33.4 ounces	66.8 ounces	133.5 ounces

10 minutes is maximum necessary contact time. One gallon of solution is sufficient to treat 135 sq. ft.

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[WATER SYSTEM TANK DISINFECTANT]:

Application	Dilution Rate	Instructions
Terminal Disinfection	1:100	Isolate the header tank at the main. Drain the line. Clean out gross soiling and debris. Refill with water and add the appropriate volume of BioBuster, mix well and let sit for 10 minutes. Flush the system to all drain off points and let sit for another 50 minutes. Drain the system and refill with clean water.
Continuous disinfection	1:100	Dose the header tank as required or apply through water system dosing equipment.

[BOOT DIPS]:

[Use a 1% solution in boot baths for the routine disinfection of footwear. Replace the solution daily or more often if the solution becomes visibly soiled.]

[POULTRY PRODUCTION]:

[HATCHERIES: BioBuster at 1% solution can be used for cleaning and disinfecting hatchers, setters, evaporative coolers, humidifying systems, transfer trucks, trays, racks, carts, sexing tables and plastic chick boxes. Saturate surfaces with a 1% solution with a coarse spray, cloth, mop or sponge and let sit for a period of 10 minutes. Allow surfaces to air dry.]

[BROILER/BREEDER HOUSES: Follow General Instructions to remove poultry and clean the area to be treated. Spray floors and walls with BioBuster at 1% solution. Thoroughly wash waterers and feeders with a 1% solution of BioBuster. After contact for 10 minutes, rinse with potable water. Do not house poultry or use equipment until treatment has dried.]

[PROCESSING PLANTS: Spray BioBuster at 1% solution to disinfect and clean walls, ceilings and floors. Saturate surfaces for a period of 10 minutes. Allow surfaces to air dry.]

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[SWINE PRODUCTION]:

[Follow General Instructions to remove swine and clean the area to be disinfected. Use a 1% solution of BioBuster for cleaning and disinfecting farrowing units, nurseries, finisher houses, processing plants, and agricultural production equipment such as trucks, rubber boots and associated livestock equipment. Saturate surfaces with a 1% solution with a cloth, mop, mechanical spray or sponge for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[EQUINE FACILITIES]:

[APPLICATIONS: For cleaning and disinfecting all hard, non-porous surfaces, equipment, utensils and instruments in equine veterinary practices and stables.

USES: Barn Aisles, Stables, Box Stalls, Tack, Equipment, Transport Vehicles and Trailers and Feed Rooms: Follow general instructions to remove animals from area to be treated. Thoroughly clean or dry clean surfaces, then wash the area manually or with pressure washer with a 1% BioBuster solution, saturating surfaces for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[BOVINE PRODUCTION]:

[Follow General Instructions to remove livestock and pre-clean the area to be treated. Use a 1% solution of BioBuster to disinfect areas associated with bovine housing, hospital quarantine pens, feedlot facilities, and agricultural production equipment: such as trucks, rubber boots and associated livestock equipment and instruments. Saturate surfaces with a 1% solution of BioBuster with a cloth, mop, mechanical spray, or sponge and allow to sit for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.]

[COMPANION ANIMALS]:

[APPLICATIONS: Use a 1% solution of BioBuster as a “one step” cleaning and disinfecting procedure (Remove visible soil before application of the disinfecting/cleaning solution) for all surfaces, equipment, instruments, utensils and cages within Veterinary Medical Hospitals, quarantine areas, laboratory animal quarters, grooming and boarding facilities, kennels, catteries and animal transportation vehicles. Saturate surfaces with a 1% solution of BioBuster with a cloth, mop, spray, or sponge and allow to remain for a period of 10 minutes. Allow surfaces to air dry. Rinse waterers and feeders with potable water before reuse.

Do not immerse metal objects for long periods - 10 minutes is maximum contact time.]

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[GREENHOUSES AND HORTICULTURE]:

[BioBuster is intended to disinfect inanimate environmental surfaces: such as floors, walls, glass greenhouse structures, ventilation equipment, utensils, trays, containers, water systems, evaporative coolers, storage rooms, and vehicles in greenhouses and other horticultural settings prior to introduction or reintroduction of plants, seeds, or soil. Must not be applied to plants, seeds, or soil. If necessary, remove or cover these items prior to use of the product.]

[For surfaces and equipment including pots, flats, trays, pruning equipment, carts and transport vehicles]:

Sweep and remove all plant debris. Surfaces should be clean at the start and any visible soil should be removed from hard non-porous surfaces prior to treatment. Use a high pressure washer to wash all surfaces to remove loose dirt. Use a dilution of 1:100 (1.3 oz powder concentrate added to 1 gallon of water). Use a dilution of 1:50 or 2.6 oz. BioBuster per gallon of clean water if surfaces to be treated have not been pre-cleaned. Apply the solution with a mop, sponge, or power sprayer, to thoroughly wet all surfaces. Heavy growth of algae or fungi may have to be scrubbed off following application.

[For evaporative coolers: Surfaces should be visibly clean prior to treatment. Treat existing algae and slime contaminated surfaces with a 1:100 dilution of BioBuster.

[BioBuster may also be used to disinfect irrigation tanks and lines. Create a 1% stock solution. Run the 1% solution through the system or soak equipment in a 1% solution. Let stand for ten minutes and then flush the system with clean water.

[AQUACULTURE]:

[BioBuster is intended to disinfect inanimate environmental surfaces associated with aquaculture production including vehicles, dip nets, boots, waders, hoses, brushes and other similar equipment. BioBuster must not be applied directly to water.]

EMERGING VIRAL PATHOGEN CLAIM

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

For an emerging viral pathogen that is a/an...	...follow the directions for use for the following organisms on the label:
Enveloped virus	Canine Parvovirus
Large, non-enveloped virus	Canine Parvovirus

Acceptable claim language:

[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 Canine Parvovirus 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 Canine Parvovirus on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal. **STORAGE:** Store in a cool dry place in tightly closed container. Keep out of reach of children. Always replace lid after use. **PESTICIDE DISPOSAL:** Pesticide wastes may be 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: Nonrefillable container. Do not reuse or refill this container.** Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.