



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

April 22, 2020

Jennifer Brandon
Authorized Agent for Bio-Lab, Inc.
Delta Analytical Corporation
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: The Works Basic Disinfectant Toilet Bowl Cleaner
EPA Registration Number: 5185-505
Application Date: April 3, 2020
Decision Number: 561524

Dear Ms. Brandon:

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 Rotavirus and Poliovirus 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

*{All text in brackets [xxx] is optional and may or may not be included on a final label.}
{All text in braces {xxx} is administrative and will not appear on a final label.}*

{Front Panel}

The Works® Basic Disinfectant Toilet Bowl Cleaner

ACTIVE INGREDIENT:

Hydrogen Chloride 9.5%

OTHER INGREDIENTS: 90.5%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

See First Aid and other precautionary statements on back label.

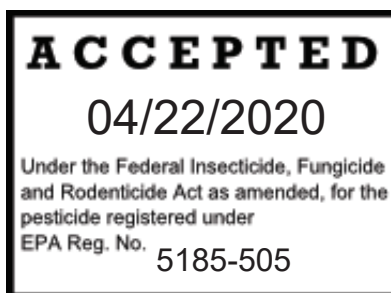
Bio-Lab, Inc.
P.O. Box 300002

Lawrenceville, GA 30049

EPA Reg. No. 5185-505
EPA Est. No. 5185-GA-1^(Z), 75371-IN-3^(FP),
88243-IN-1^(AS), 93405-IN-1^(DP)

Letter Designation in Lot Code Printed Above or
Below On Container Identifies Actual
Establishment

Net Contents: *{as indicated on container}*



{Front/Back Panel}

{INTRODUCTORY 6-mos. CLAIMS – will only appear on graphic labels for the first 6 months the product is produced}

[New] [Improved] [Formula] [Cap] [Fragrance] [Pack] [Package] [Scent] [Size]

{PACKAGING CLAIMS}

[33% MORE than other leading national brands†] *{When sold in 32 fl oz (quart) size}*

[† Compared to 24 fl oz of other leading national brands.]

[Bonus 33%] [33% Free] [8 oz. For Free] [32 oz. for the price of 24 oz.]

[24 oz. for the price of 16 oz.]

[Great] [Bonus] [Economy] [Value] [Trial] [Pack] [Size] [Mega Value Pack] [Mega Value Size]

[2 for 1 Pack] [2 in 1 Pack] [_x_FL. OZ.]

[2 PACK] [3 PACK] [4 PACK] [6 PACK]

[Place 1 in each bathroom] [Buy x get x free] [x% discount] [x% more free] [x% more product]

[Best value bottle]

[Buy me again]

[Contains up to x uses]

[Convenient cap]

[Easy grip bottle]

[Easy to close]

[Easy to reach under the rim]

[Easy] [Easier] to [open] [squeeze] cap]

[Easy to use [bottle]]

[Helps reach under the rim]

[Leak-proof cap]

[For use in toilets & urinals]

[For use with Standard and Low Volume toilets]

{Cleaning Claims}

[Cleans & Deodorizes]

[Deodorizes]

[Deep cleaning] [Easy to use] [Non-abrasive] [Rust destroying] [Tough stain] [Formula]

[Lime & Rust Remover] [Lime Scale Remover] [Lime Scale & Rust Remover]

[Removes Rust, Lime Scale, & Hard Water Stains]

[Fast] [Easy] [Effective] [Toilet Bowl Cleaner]

[Removes Rust Stains and Lime Deposits]

[Breaks down] [Cleans] [Cleans away] [Destroys] [Dissolves] [Easily] [Penetrates] [Quickly]

[Removes] [Stubborn] [Tough] [Hard Water] [Lime Scale] [Mineral] [Rust] [Stains] [Deposits]

[Toilet Rings]

[Completely] [Easily] [Effectively] [Quickly] [Thoroughly] [Cleans] [Shines] [Whitens]

[Deodorizes]

{Front/Back Panel}

[ESSENTIALS‡]

[‡See back panel.]

{Pesticide Claims}

{If “germs” claim is made, must list both bacteria and viruses on back panel.}

[Bacteria Fighting Action]

[Bacteria + Stain Fighting Action]

[Bacteria + Virus⁺ + Stain Fighting Action]

[Bacteria, Virus⁺ + Stain Fighting Action]

[Germ* Fighting Action]

[Cleans & Disinfects]

[Kills 99.9% of Household Germs*]

[Kills 99.9% of Household Germs* in the Bowl]

[Kills 99.9% of Household Bacteria + Viruses⁺*]

[Fast] [Easy] [Effective] [Toilet Bowl Disinfectant]

[Kills 99.9% of Household Bacteria*]

[Kills Household Bacteria*]

[Kills Household Germs*]

[Kills Household Germs* in the Bowl]

[Kills Household Bacteria + Viruses⁺*]

[Antibacterial] [Antibacterial Action] [Antimicrobial]

[Antiviral⁺]

[Disinfectant]

[Disinfects]

[Effective in 400 ppm hard water [and 5% soil]

[Kills Viruses⁺]

[The Works Basic Disinfectant Toilet Bowl Cleaner can be use as a disinfectant in homes, schools, and offices.]

[*Kills the following Household Bacteria [and Viruses⁺]]

[•*Salmonella enterica*] [•*S. enterica*]

[•*Pseudomonas aeruginosa*] [•*P. aeruginosa*]

[•*Staphylococcus aureus*] [•*S. aureus*]

[•*Enterococcus faecalis*] [•*E. faecalis*]

[•*Shigella dysenteriae*] [•*S. dysenteriae*]

[•*Klebsiella pneumoniae*] [•*K. pneumoniae*]

[•*Escherichia coli*] [•*E. coli*]

[•*Rotavirus*⁺]

[•*Poliovirus*⁺]

[•Human Immunodeficiency Virus type 1⁺] [•HIV-1 AIDS Virus⁺]

[‡This product combines both disinfection and cleaning action for the essentials of toilet bowl maintenance.]

Emerging Viral Pathogens Claims

[This product qualifies for emerging viral pathogen claims per 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 emerging viral pathogens from the following viral categories:]

For an emerging viral pathogen that is a/an:	...follow the directions for use for the following organism on the label:
Enveloped Virus	Rotavirus; Poliovirus
Large Non-Enveloped Virus	Poliovirus

[Statements must adhere to one or both of the following formats:]

[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 **[name of supporting virus(es) – see table above]**] 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 **[name of supporting virus(es) – see table above]**] on hard non-porous surfaces. Refer to the **[CDC or OIE]** website at **[website address]** for additional information.

[These statements shall not appear on marketplace (final printed) labels]

{Back Panel}

[Will Not Harm Septic Systems]

READ ENTIRE LABEL BEFORE USING - FOR TOILET BOWL USE ONLY

DIRECTIONS FOR USE:

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

ATTENTION: DO NOT MIX WITH CHLORINE-TYPE BLEACHES OR OTHER HOUSEHOLD CHEMICALS.

DO NOT SPILL OR PLACE ON COUNTERTOP, CARPET, FLOORING, BATHTUB, SINK, ENAMEL OR CHROME SURFACES. CLEAN SPILLS IMMEDIATELY! FOR TOILET BOWL USE ONLY!

TO OPEN CHILD RESISTANT CAP:

{Closure instructions for press (push down) and turn CR cap}

Hold bottle firmly, push down on cap and turn counter-clockwise. **Be careful not to squeeze bottle when removing cap.** To reseal, turn cap clockwise until tightly closed.

{Closure instructions for flip spout dispensing CR closure}

DO NOT squeeze bottle when opening or closing. Wearing rubber gloves, use your fingernail or pen point and apply slight backward pressure to the ridge of flip top. Once flip top is raised slightly, the flip top can be lifted completely. Always re-close after use and store with cap closed.

{Closure instructions for squeeze and twist CR closure}

DO NOT squeeze bottle when opening or closing.

1. Place fingers on ridges at base of cap.
2. Squeeze cap firmly and turn counterclockwise until it stops. **Do not remove cap.**
3. To close, turn cap clockwise. Close tightly.

TO CLEAN BOWL: Flush toilet. Raise toilet seat. Open cap and point bottle down into bowl. Carefully direct product onto sides of the bowl and under the rim. Close cap. Brush to cover all surfaces of the bowl. Flush toilet. For heavily stained bowl, repeat above procedure.

TO CLEAN TANK: Empty tank and apply to sides. Do not apply directly to internal working parts. Brush then fill and flush.

TO DISINFECT: Remove heavy soil and deposits from surfaces with bowl brush. Apply 8 fl. oz. of product onto all interior bowl surfaces. Let product remain 10 minutes before brushing, making sure to get under the rim. Flush with clean water.

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{HIV-1 AIDS Virus directions will be included if HIV virus is claimed on label}

KILLS HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 [HIV-1/AIDS Virus] ON PRECLEANED 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/body fluids and in which the surfaces/objects likely to be soiled with blood/body fluids can be associated with the potential for transmission of HIV-1 (associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS.

PERSONAL PROTECTION: When handling items soiled with blood or body fluids, use disposable [protective] [latex] gloves, gown, masks and eye protection.

CLEANING PROCEDURES: Blood/body fluids must be thoroughly cleaned from surfaces/objects before application of [this product] [The Works Basic Disinfectant Toilet Bowl Cleaner].

CONTACT TIME: Allow surface to remain wet for 10 minute.

DISPOSAL OF INFECTIOUS MATERIAL: Blood/body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER: CORROSIVE. Causes skin burns and irreversible eye damage. Harmful if swallowed or absorbed through skin. Do not get in eyes, on skin, or on clothing. Wear goggles or safety glasses, protective clothing, and rubber (or chemical-resistant) gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse. Do not breathe vapor or fumes. Keep out of reach of children.

CHEMICAL HAZARDS: Do not use with chlorine –type bleach or any other chemical products, to do so may release hazardous gases creating a risk of serious injury, including death.

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 SWALLOWED:** Call 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. **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.

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Have the product container or label with you when calling a poison control center or doctor, or going for treatment. [IN CASE OF MEDICAL EMERGENCY, CALL [1-303-623-5716] [1-877-800-5553] [telephone number supplied by supplemental registrant].]

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

STORAGE AND DISPOSAL: STORAGE: Keep this product in original tightly closed container when not in use. Store in a cool, dry, well ventilated area. Store out of reach of children. **PESTICIDE DISPOSAL:** To avoid waste, use all material in this container according to label directions. **CONTAINER DISPOSAL:** Non-refillable container. Do not reuse or refill this container. Offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions.

NOTE: Buyer assumes all responsibility for safety and use not in accordance with directions.

Questions? Comments?
1-800-xxx-xxxx