



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 24, 2023

Jeremy Malone
Regulatory Agent for,
Flex AI, LLC
Electronic Transmittal: [jeremy@springregulatory.com]

Subject: Label Amendment: Addition of Emerging Viral Pathogens
Product Name: Bio-Spear Sanitizing Wipes
EPA Registration Number: 87656-3
Received Date: August 18, 2022
Action Case Number: 00386238

Dear Mr. Malone:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 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. Pursuant to 40 CFR 156.10(a)(6) 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 (small non-enveloped, 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 (identify label viruse(s)) 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 FIFRA and is subject to review by the Agency. See FIFRA section 2(p)(2) 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, FIFRA section 12(a)(1)(B). 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 Karen M. Leavy via email at Leavy.Karen@epa.gov.

Sincerely,



Tara Flint Silva, Acting Product Manager 31
Regulatory Management Branch I
Antimicrobials Division
Office of Pesticide Programs

Enclosure: stamped label

ACCEPTED

01/24/2023

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 87656-3

[Denotes Optional Text]
{Denotes Notes to EPA Reviewer}
{Front Panel Start}
{Label version date: 05/05/2023}

Bio-Spear Sanitizing Wipes

For use on hard, non-porous surfaces

[[*] BACTERICIDAL] [[*] [BACTERIOSTATIC] [[*] [HOSPITAL DISINFECTANT] [[*] [BROAD SPECTRUM
DISINFECTANT] [[*] [ANTIMICROBIAL] [VIRUCIDAL*]

[For Household Use]

ACTIVE INGREDIENTS:

3(trihydroxysilyl)propyl dimethyloctadecyl ammonium chloride	0.54%
1-Decanaminium, N-decyl-N,N-dimethyl-, chloride.....	0.90%
INERT INGREDIENTS†:.....	98.56%
TOTAL.....	100.00%

† Does not include the weight of the dry [towelette] [[or] wipe].

KEEP OUT OF REACH OF CHILDREN

WARNING

[See [left] [side] [right] [back] [bottom] [other] panel for additional precautionary statements and first aid.]

EPA Reg. No. 87656-3

EPA Est. No. 87656-XX-X

Net Contents: # ___ lbs. (___ ozs.)

Pre-Saturated [towelette] [wipe] # x # in.

{End Front Panel}

Reorder No.

[Packed For:]	FLEX AI, LLC
[Distributed By:]	5300 Derry Street
[Sold By:]	Harrisburg, PA 17111

{Note to Reviewer: The First Aid section can be in table or paragraph format}

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• 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 further advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For non-emergency and general information on product use, etc., information pertaining to this product, call the National Pesticides Information Center at 1-800-858-7378 (NPIC web site: npic.orst.edu/). For emergencies, call the poison control center 1-800-222-1222. For Chemical Emergency ONLY (spill, leak, fire, exposure or accident), call CHEMTREC at 1-800-424-9300.	

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. 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.

{Kill Claims:}

[Hard, Non-Porous Non-Food Contact Surface Sanitization]

Bio-Spear [Sanitizing Wipes are] [is] effective against the following microorganisms in 5 minutes on hard, non-porous, non-food contact surfaces²:

- Staphylococcus aureus [Staph] [ATCC 6538]
- Klebsiella aerogenes [ATCC 13048]

[Hospital and General Disinfection]

Bio-Spear [Sanitizing Wipes are] [is] effective against the following microorganisms in 10 minutes on pre-cleaned hard, non-porous surfaces²:

- Pseudomonas aeruginosa [Pseudomonas] [ATCC 15442]
- Salmonella enterica [Salmonella] [ATCC 10708]
- Staphylococcus aureus [Staph] [ATCC 6538]

[Virucidal*]

Bio-Spear [Sanitizing Wipes are] [is] effective against the following microorganisms in 10 minutes on pre-cleaned hard, non-porous surfaces²:

- Human Coronavirus [ATCC VR-740] [Strain 229E]
- Influenza A virus [ATCC VR-544] [Strain A/Hong Kong/8/68]
- Adenovirus [Type 5] [ATCC VR-5] [Strain Adenoid 75]

DIRECTIONS FOR USE

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

Bio-Spear [wipes] [towelettes] are intended for use on hard, non-porous, non-food contact surfaces.

{Reviewer Note: For labels that list medical premises and metal and / or stainless steel surfaces, one of the following statements must be used:}

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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.]

{or}

This product is not for use on medical device surfaces.

[Use A or B as applicable depending on the container type.]

[A - canister]

Dispenser Directions:

To start feed, remove cover and discard seal. From center of [towelette] [wipe] roll, pull up a [towelette] [wipe] corner, twist it into a point and thread it through the hole in the container cover. Pull through about one inch. Replace cover. Pull out first [towelette] [wipe] and tear off at a 90° angle. Remaining [towelettes] [wipes] feed automatically, ready for next use. When not in use, keep center cap closed to prevent solution loss.

[B - packet]

Packet Directions:

Open packet, remove [towelette] [wipe] and unfold.

[Directions for use for A and B]

{Reviewer Note: Deodorizing and Cleaning Instructions are optional on the end label. Sanitizing Instructions are optional on the end label unless claims are made on the label. Disinfection Instructions are optional on the end label unless claims are made on the label. One of the three sections is required.}

Deodorizing and Cleaning Instructions:

Use one Bio-Spear [towelette] [wipe] to completely wipe surface clean with this product. Let air dry.

Sanitizing Instructions:

Bio-Spear is a one-step Sanitizing product. Completely pre-clean surface of all visible debris. Wipe surface; use enough wipes for treated surface to remain visibly wet for 5 minutes. Allow to dry thoroughly before use/no rinsing necessary. Do not reuse dried out wipes.

Disinfection Instructions:

To pre-clean: Use one Bio-Spear [towelette] [wipe] to completely wipe surface clean with this product. Repeat, if necessary, until surfaces are visibly clean.

For use as a hard, non-porous non-food contact surface disinfectant/virucide*: Wipe pre-cleaned surface; use enough wipes for treated surface to remain visibly wet for 10 minutes. Allow to dry thoroughly before use/no rinsing necessary. Do not reuse dried out wipes.

Directions for Floor Wipe Use:

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

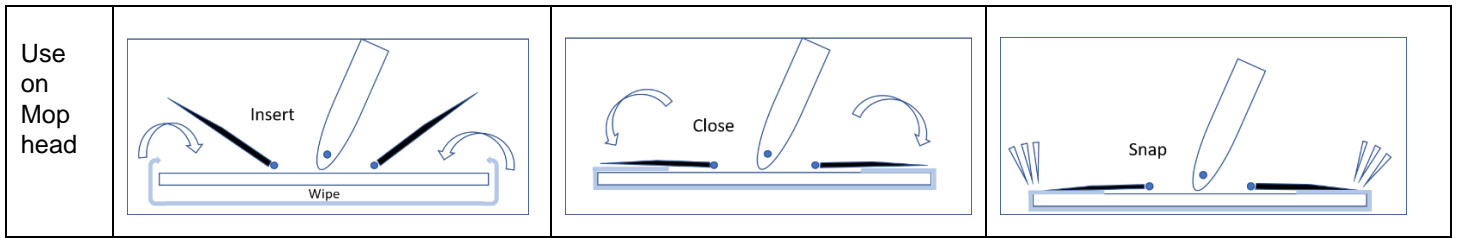
To Clean and Deodorize: Wipe surface with wipe. Let air dry. Discard used wipe in trash. Do not flush [in toilet].

To Clean and Disinfect: Pre-clean sealed floors according to use directions for disinfection. [Attach a presaturated wipe to the mop head using the [velcro] [fasteners] provided.] Thoroughly wet floor with wipes. [Change wipe when soiled.] or [Replace with a fresh wipe once visibly soiled or no longer thoroughly wetting the surface.] Allow surface to remain visibly wet for 10 minutes. Let air dry. On average, one wipe will clean [10] [x] square feet of floor. For a larger area you may need to use more than one wipe. Discard used wipe in trash. Do not flush [in toilet]. Do not use to disinfect food contact surfaces, dishes, glassware or utensils. Do not use as a diaper wipe or for personal cleansing. Contact manufacturer of wood floors prior to use.

[Spot test on an inconspicuous area before use.]

Keep container flat and lid securely closed to keep cloths moist.

{Optional representative graphic}



TO USE WITH MOP:

1. Place wipe on hard, non-porous surface.
2. Place mop on top of wipe.
3. Wrap wipe around head of mop and between head and insert.
4. Close insert onto wipe and sweeper head until it snaps.
5. Begin wiping. No rinsing required.
6. After use, remove soiled wipe and discard in trash. Do not flush [in toilet].

[Use A or B as applicable depending on the container type.]

[A - canister]

STORAGE AND DISPOSAL

Do not contaminate food, feed or water with storage or disposal.

Pesticide Storage: Store wipes in original container.

Pesticide Disposal: [Towelette] [Wipe] - Do not reuse [towelette] [wipe]. Dispose of used [towelette] [wipe] in trash.

Container Handling: Dispenser - Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. [Wrap container and discard in trash.]

[B - packet]

STORAGE AND DISPOSAL

Do not contaminate food, feed or water with storage or disposal.

Pesticide Storage: Store wipes in original container.

Pesticide Disposal: [Towelette] [Wipe] - Do not reuse [towelette] [wipe]. Dispose of used [towelette] [wipe] in trash.

Container Handling: Nonrefillable container. Do not reuse or refill this container. Offer for recycling, if available. [towelette] [wipe] - Do not reuse [towelette] [wipe]. Dispose of used [towelette] [wipe] and empty packet in trash.

{Reviewer notes on Use Sites:

-Lists of uses and use sites may be used partially or in their entirety.

-If listing Use Sites from this section, the phrase beginning with "This product..." below must be included unless referenced from Marketing claims section

-The following paragraph will be included when the marketing label references health care use :

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 critical or semi-critical medical devices prior to sterilization/high-level disinfection. }

{Use Sites:}

This product can be used on hard, non-porous surfaces [in] [at] [the following locations]: Acute care facilities, air transport facilities, airports, airplane interiors, amusement parks, ambulatory care centers, ambulatory care facilities, anesthesia areas, animal/pet care facilities, animal control facilities, animal control vehicles, animal breeding facilities, animal detention facilities, animal hospitals, animal laboratories, animal research facilities, animal rescue shelters, animal shelters, animal show facilities, animal trailers, apartments, arboretums, arcades, athletic training facilities, athletic locker rooms, automatic teller machine (ATM) facilities, auto facilities, autopsy rooms, avian care facilities, avian facilities, avian units, bakeries, banks, barber shops, bathroom facilities, bathrooms, bedrooms, blood banks, banquet hall facilities, bioskill laboratories, blood drawing centers, blood units, blood pheresis facilities, body piercing salons, body service facilities, body storage facilities, botanical gardens, bowling alleys, brushes, bus facilities, bus stations, cab facilities, cadaver processing areas, canine facilities, canine units, cardiac catheterization labs, cardiac catheterization laboratories, cash dispensing machines, casinos, Cat-scan ([laboratories] [labs]), central instrument reprocessing facilities, child care facilities, clean rooms, clinical areas, colleges, condominiums, convention facilities, conference centers, conference room fixtures, correctional facilities, CS ([laboratories] [labs]), CT ([laboratories] [labs]), daycare centers, day care schools, day spas, delivery units, dental care facilities, dental laboratories, dental offices, detention facilities, dialysis centers, dialysis units, dissection labs, doggy day care centers, drug preparation facilities, drug preparation rooms, early learning centers, electrolysis facilities, emergency medical service (EMS) units, emergency rooms, endoscopy centers, endoscopy facilities, endoscopy departments, entertainment facilities, environmental services facilities, equine facilities, equine units, esthetician facilities, eye care facilities, exam rooms, examination rooms, feline facilities, feline units, fire departments, fire departments, florists, non-food contact surfaces in food processing facilities, foot spas, foreign currency exchange facilities, forestry services, funeral homes, gaming facilities, garden centers, general public facilities, GI ([laboratories] [labs]), golf courses, grocery stores, grammar schools, grooming facilities, grounds keeping services, gymnasiums, gyms, habitats, hair salons, health clubs, health club facilities, health care facilities, ambulance helicopter interiors, high schools, holding cells, home care patient rooms, home health care facilities, homes, hospice rooms, hospitality facilities, hospitals, hotels, household bathrooms, housekeeping rooms, hydrotherapy facilities, hydrotherapy rooms, infant care facilities, infant/child care equipment surfaces, in-home health care rooms, instrument reprocessing areas, intensive care units (ICUs), isolation rooms, jails, kiosks, kindergartens, kitchens (non-food contact), labor units, laboratories, landscaping services, laser eye surgery centers, laundry rooms, lawn services, learning institutions, limousine facilities, living rooms, lockup facilities, long-term care facilities, lunchrooms (non-food contact), medical facilities, medical offices, medivans, MICUs, middle schools, money handling facilities, morgues, mortuary facilities, mortuaries, motels, movie theaters, MRI facilities, MRI ([laboratories] [labs]), nail salons, neonatal intensive care units (NICUs), newborn nurseries, nuclear medicine facilities, nurseries, nursery schools, nursing homes, occupational therapy centers, occupational therapy facilities, oncology medical facilities, operating rooms, ophthalmology centers, ophthalmology facilities, ophthalmology units, optometric offices, oral health care facilities, orthodontic offices, outpatient care facilities, outpatient facilities, outpatient surgery centers, patient care rooms, pathology rooms, pediatric units, pedicure salons, personal care service facilities, pet areas, pet homes, pet motels, pet spas, pet stores, pharmacies, physical therapy centers, physical therapy facilities, plasma pheresis centers, plasma pheresis facilities, pheresis units, post-op rooms, post-operative rooms, pre-op areas, pre-operation areas, pre-schools, primary care facilities, prisons, public facilities, public bathrooms, public transportation facilities, radiology rooms, non-medical reception areas, medical reception areas, recovery rooms, recreation facilities, rehabilitation facilities, respiratory therapy facilities, reptile habitats, restaurants, restroom facilities, retail stores, rodent facilities, rodent units, salon settings, schools, sleeping rooms, scope reprocessing rooms, shopping malls, sick room facilities, sick rooms, skilled nursing centers, skin care facilities, skin care salons, snack shops, spas, SPD ([laboratories] [labs]), tanning salons, tattoo studios, taxi facilities, taxi cab facilities, theaters, train facilities, train stations, transport vehicles, transportation waiting rooms, tree services, universities, urgent care centers, urgent care facilities, veterinary hospitals, waiting rooms, weight training facilities, X-ray rooms, x-ray equipment surfaces, zoos.

{Reviewer notes on Surfaces:

-Lists of surfaces may be used partially or in their entirety.

-If listing Surfaces from this section, the phrase beginning with "This product..." below must be included unless referenced from Marketing claims section

-The following paragraph will be included when the marketing label references health care use :

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 critical or semi-critical medical devices prior to sterilization/high-level disinfection. }

{Surfaces:}

This product can be used on the following hard, non-porous surfaces: inanimate surfaces such as those made of acrylic, metals (aluminum, brass, copper, stainless steel, chrome), sealed granite, glass, plastic (i.e., polycarbonate, polypropylene, polyvinylchloride, polystyrene, PVC), clear plastics, hard, non-porous rubber, Plexiglas®, vinyl as well as coated, laminated and painted surfaces, air evacuation transport units, air transport units, air vents surfaces, airplane fixtures, airplane interiors, ambulance equipment surfaces, ambulances, amusement machine surfaces, analgesia equipment surfaces, anesthesia machines, animal cages, animal habitats, apnea monitors, aquariums, athletic facility fixtures, athletic equipment, athletic protective equipment, ATM surfaces, ATM touch buttons, tables, backboards, balloon pumps, bank teller surfaces, bar tops, bassinets, bathing tubs, bathroom facilities, bathroom fixtures, bathroom surfaces, bathtubs, bed railings, beds, bedside devices, bedside tables, bedside stands, biohazard team equipment, biological monitoring devices, bird cage surfaces, birthing room fixtures, blood bank equipment surfaces, blood drawing surfaces, blood pressure equipment, blood pressure units, bowls, breathing monitors, cabinets, cages, call buttons, cardiac monitors, cash register surfaces, cash registers, cat litter boxes, carts, central supply equipment, chainsaw blades, chairs, changing tables, chest pumps, classroom fixtures, clipper blades, clippers, coated mattresses, coated pillows, coin counter surfaces, coin dispensers, collars, colon equipment surfaces, combs, commodes, computer keyboards, computers, computer screens, computer touch-screens, counters, countertops, external surfaces of CPAP masks, external surfaces of CPAP units, CPR training devices, CPR training manikins, crash carts, cribs, CT equipment, curing lights, cuspidors, dental trays, dental chair surfaces, dental equipment surfaces, dialysis treatment equipment surfaces, diaper changing stations, diaper pails, dictating machines, dissection work tables, diving equipment, external surfaces of diving masks, door handles, door knobs, drained whirlpool tank surfaces, drinking fountain exteriors, drug preparation equipment, drug preparation hoods, dry suits, dumbbells, elevator buttons, elevator panels, emergency room stretchers, emergency medical technician units, emergency rescue squad vehicles, EMT units, embalming tables, empty whirlpool tanks, environmental patient care fixtures, equipment counters, ER stretchers, ER equipment surfaces, escalator and moving walkway handrails, exam equipment exam lights, exam room lights, exam room surfaces, exam tables, examination equipment, examination lights, exam room lights, examination room surfaces, examination tables, exterior surfaces of [refrigerators,] [microwaves,] [food processors,] (allow to come to room temperature before treatment), exterior toilet surfaces, eye wear, eye glasses (do not use on contact lenses), face shields, faucets, finger print counters, first call stretchers, fish tank aerators, fish tank filters, fish tank gravel, fish tanks, fishing waders, flea combs, sealed floors, [sealed] [glazed] flower pots, food delivery carts, foot spa bowls, Formica®, frequently touched surfaces, furniture, gaming machines, garbage cans, garbage compactors, garden equipment, garden storage bins, garden tools, glucometers, glucose meters, goggles, gonial lenses, grass mower blades, grocery carts, grooming facility surfaces, grooming tables, hair care stations' fixtures, hair brushes, hair clippers, hair combs, hair cutting implements, hair dryers, handcuffs, handrails, hand-pieces, hazmat team equipment, hearse interiors, helicopters, high chairs, high-touch areas, home care equipment surfaces, horse trailers, hospice rooms, household fixtures, empty Hubbard tanks, empty hydrotherapy units, hygiene treatment surfaces, hyperbaric chamber surfaces, IC pumps, immobilization devices, implements, incubators, infant care equipment, infant care warmers, infant changing tables, infant incubators, infant seats, infant transport incubators, infant warmers, infant warming equipment, Isolettes®, instrument reprocessing equipment, instrument trays, interior tubing lumens, IV poles, IV stands, IV pump surfaces, infusion pump surfaces, kennels, keyboards, kidney dialysis equipment surfaces, kick buckets, non-food contact kitchen fixtures, kitty litter boxes, kitty litter scoops, lab benches, lab fixtures, laboratory benches, laboratory equipment and surfaces, laboratory fixtures, labor and delivery room surfaces, laundry rooms, lights, light lens covers, light pull chains, light switches, lights, litter boxes, locker room benches, lockers, lockup facility fixtures, loupes, manicure implements, marine vessel interiors, exterior surfaces of hard, non-porous masks, mayo stands, medication carts, microkeratome surfaces, microscopes, monitors, MRI equipment surfaces, nail/hair care implements, nail implements, nail station fixtures, nail station tables, non-critical devices, noncritical operating room lights, non-porous vinyl, operating room surfaces, operating room tables, OR lights, OR surfaces, OR tables, non-food contact surfaces of [High chairs,] [stoves (allow to become to room temperature before treatment),] [vanity tops,] [tiles,], non-food/feed contact surfaces, non- food/feed preparation surfaces, non-food contact surfaces in food preparation areas, non-porous hazmat suits, non-porous plastic-covered menus, hazmat suits,

([laminated] [plastic])-covered menus, nursing station fixtures, OB/Gyn surfaces, OB/Gynecology department surfaces, occupational therapy surfaces, operating room lights, optical wear (excluding contact lenses), organ scales, oxygen hoods, oxygen units, paramedic units, patient care fixtures, patient bedrails, patient chairs, patient lifts, patient transport carts, patient transport vehicles, pedicure chairs, pedicure chair tubs, pedicure implements, PEEP units, pet carrier surfaces, pet care surfaces, pharmacy counters, pharmacy surfaces, phototherapy lights, physician office surfaces, physical therapy (PT) equipment surfaces, pruning shears, plastic mattress covers, play-care equipment, Plexiglas® hoods, poker machine surfaces, police and fire vehicles, pooper scoopers, prisoner benches, protective eye wear, pulse oximeters surfaces, pumps, rails, reception area fixtures, recreational devices, exterior surfaces of refrigeration units, remains bags, remote controls, reptile habitats, external surfaces of respirator ventilators, external surfaces of respirators, external surfaces of respiratory therapy equipment, salon fixtures, salon surfaces, scales, scissors, school fixtures, school lockers, scoop stretchers, scuba equipment, self-contained breathing apparatus (SCUBA) equipment, shampoo bowls, shears, shopping carts, shower doors, shower surfaces, shower stalls, sinks, skin care equipment surfaces, exterior surfaces of dermal infusion equipment, slit lamps, slot machines, slot machine handles, slot machine surfaces, soap containers, soap dishes, SPD equipment, spine back boards, exterior surfaces of refrigerator units (allow to come to room temperature before treatment), splinting devices, squad benches, stalls, stair-chairs, stethoscopes, stools, stretchers, external surfaces of suction devices, external surfaces of suction machines, external surfaces of suction units, supply cabinets, surgical tables, tables, tabletops, tanning beds, telemetry equipment, telephones, toilet facilities, exterior surfaces of toilets, toilet seats, toilet training equipment, training room surfaces, tonometer equipment surfaces, tonometer tip surfaces, tools, touch screens, trash can lids, trash cans, treatment hoods, transport vehicle interiors ([train] [airplane] [helicopter] [automobile] [bus] [taxi] [limo] [ambulance] [patient] [yachts] [cruise ship interior] [transport vehicle]) surfaces, tree saws, tubing, turf equipment, turf equipment blades, TV remote controls, unplugged hair driers, van fixtures, van interiors, vehicle interiors, vending machine surfaces, external surfaces of ventilators, veterinary operating room lights, veterinary operating room tables, veterinary equipment surfaces, video poker machines [exteriors], walkers, washable nail files, waterproof mattresses, weight-lifting surfaces, weight machines, weight scales, weight training equipment, wheelchairs, window sills, workstations, workout machines, x-ray units and [frequently touched] [high-touched], ([surfaces][areas]).

{Reviewer notes on Marketing Claims:

- Lists of uses and use sites may be used partially or in their entirety.
- All footnotes are on the last page, unless they are part of EPA's mandated text.
- The word "and" may be substituted with "&".
- Optional text may be placed anywhere on the label/container.
- “This Product” can be replaced with product name anywhere on the label.}

{Optional Marketing Claims}

CLEANING CLAIMS:

- Clean[s]
- Clean more with less
- Clean to a virtually streak-free shine
- Cleans [away] [up] dirt, dust and hair
- Convenience of a wipe [a cloth]
- [Everyday] [Regular] Cleaning Wipes
- Great on kitchen grease
- Grimy messes
- [Heavy] [Light] duty cleaning [jobs]
- Helps you finish cleaning [fast] [quickly]
- Leaves your bathroom fresh and clean
- Makes [your job] cleaning [easier] [easy]
- No [mixing] [mess] [and / or fuss] [no muss]
- No rinsing required
- No rinse needed
- No rinse
- No sprays, no sponges, no mess
- One step cleaning
- Powers through [tough messes] [the dirt] [the grime]
- Powers through tough messes
- Cleans and Protects
- Quick easy clean-ups.
- Touch Up
- Tough cleaning [made easy] [made easier]
- Wipes are good for quick touchups

DEODORIZING CLAIMS:

- Deodorize[s]
- Don't just mask odors – [eliminate][neutralize] them
- [Eliminates][Neutralizes] odors on contact
- Don't just mask odors [eliminate] [neutralize] [prevent] the bacteria that causes them
- Deodorizes, Works wet and dry
- Keeps on working even after it dries against odor-causing bacteria ¹
- Deodorizing activity for up to 15 days ¹
- Bacteriostatic activity for up to 15 days against odor-causing bacteria ¹
- Provides bacteriostatic activity against odor-causing bacteria for up to 15 days on hard surfaces including {insert from Surfaces section} ¹
- This product deodorizes by killing bacteria that cause offensive odors.
- This product [improves labor results by] effectively controls [controlling] malodors.

CLEANING AND DEODARIZING CLAIMS:

- A fresh take on tough cleaning
- An effective way to clean and deodorize against odor-causing bacteria.
- Eliminate dirt and [neutralize] odor
- Power[s] through [tough] [messes] [dirt] [and grease] and [help[s]] [eliminate[s]][neutralize[s]] odors

ANTIBACTERIAL CLAIMS:

- Antibacterial
- Antibacterial Formula
- [antibacterial] [disinfecting] [sanitizing]
- [Bacteriostatic] [Disinfecting] [Sanitizing] Wipes
- Can be used as a daily [Disinfecting] [Sanitizing] Wipes
- Clean and [disinfect] [sanitize]
- Clean and [disinfect] [sanitize] [high touched] hard, non-porous surfaces in minutes[!]
- Cleans and [disinfects] [sanitizes] hard, non-porous surfaces
- Daily [Surface] [Disinfectant] [Sanitizer] [Cleaner]
- [Designed] [Built] for Everyday [Disinfecting] [Sanitizing] [Cleaning] [wiping]
- [Disinfect] [Sanitize] Surfaces [Daily] [Everyday]
- [Disinfecting] [Sanitizing] Formula
- [Disinfecting] [Sanitizing] Wipes
- Disinfecting wipes with scrubbing action
- [Disinfects] [Sanitizes]
- Effective sanitizer in the presence of 5% serum contamination
- Eliminates 99.9% of bacteria[!]
- Eliminates 99.9% of [Pseudomonas aeruginosa] [Salmonella enterica] [Staphylococcus aureus] in 10 minutes[!]
- Everyday [Surface] [Disinfectant] [Sanitizer]
- Great for Everyday [Disinfecting] [Sanitizing] [Wiping]
- Hospital Disinfectant
- Broad Spectrum Disinfectant
- Kills 99.9% of [Bacteria] [Viruses*] [Bacteria and Viruses*]
- [Kills] [Eliminates] [Removes] 99.9% of {Insert pathogen or pathogens from lists on page 2} on pre-cleaned, hard, non-porous environmental surfaces
- [Kills] [Eliminates] [Removes] 99.9% of bacteria [Viruses*] [Bacteria and Viruses*]
- [Kills] [Eliminates] [Removes] 99.9% of bacteria, leaves [leaving] surfaces [clean and] disinfected
- [Kills] [Eliminates] [Removes] 99.9% of {Insert organisms from Kill Claims list}
- Kills, Cleans and Deodorizes
- Kills 99.99% of odor causing bacteria
- Leaves surfaces disinfected
- Reduce cross contamination between treated hard non-porous surfaces
- Remove [99.9% of] [Bacteria] [from] [Kitchen] [Bathroom] [Office] Hard, Nonporous Surfaces
- [Sanitize][Disinfect] hard, non-porous surfaces of bathroom[sink[s]] [faucet[s]] [outer surfaces of toilet[s]] [flush handle][seat] [light switch] [door][handle][knob]
- [Sanitize][Disinfect] the hard, non-porous surfaces of [cabinets], [chairs], [counter[s]top[s]], [shower][door[s]][stalls], [bathtub[s]], [sink[s]], [vanities], [vanity][top[s]], [bathroom][fixture[s]][faucet[s]]
- [Sanitize][Disinfect] the hard, non-porous external surfaces of [personal protective equipment][PPE][respirators][full face breathing apparatus]
- [Sanitize][Disinfect] [waiting rooms] [public areas]
- [Sanitize][Disinfect] [surfaces][items][:][such as] [cribs] [tables] [tabletops] [counters] [countertops] [appliances] [sinks] [glazed tiles] [light switches] [door handles] [railings] [telephones] [trash][garbage][can[s]][receptacle[s]][bin[s]]
- The smart [way to] clean [and disinfect] [and sanitize]
- The wipe that cleans [up] [stubborn] [stuck-on]
- This product will clean and disinfect hard, non-porous surfaces.
- This product is a [hospital] disinfectant that is effective against a broad spectrum of bacteria²
- This product [Kills] [eliminates] 99.9% of [kitchen] [bathroom] bacteria.
- This product [kills] [eliminates] 99.9% of bacteria
- This product delivers non-acid disinfectant and cleaning performance
- This product will disinfect, clean and deodorize surfaces in rest rooms and toilet areas, behind and under sinks and counters, garbage cans and garbage storage areas, and other places where bacterial growth can cause malodors.
- Two in one action -cleans and sanitizes
- [With proven] Antibacterial Action

SANITIZATION CLAIMS:

- 99.99% effective against [Staphylococcus aureus][Klebsiella aerogenes] in [just] 5 minutes [!]

- 99.99% effective against bacteria in [just] 5 minutes [!]
- Kills 99.99% of bacteria in [just] 5 minutes [!]
- Kills 99.99% of bacteria²
- Kills 99.99% of [Staphylococcus aureus][Klebsiella aerogenes] in [just] 5 minutes [!]
- Sanitize [high touched] surfaces in [just] minutes[!]
- Sanitize[s]
- Sanitizing Wipes
- [This product or product name] is an effective sanitizer against [Staphylococcus aureus][Klebsiella aerogenes].

USAGE CLAIMS:

- Bonds to surfaces for up to 15 days[!] providing bacteriostatic activity against odor-causing bacteria¹
- Ready to Use
- Reapply every 15 days[!] for bacteriostatic activity against odor-causing bacteria¹
- For Institutional and Industrial Use
- Multi-surface (hard, non-porous) [use]
- Save time with this product[!]
- Saves Time
- Kitchen and Bath [wipes] [towelettes] [for Hard, Non-Porous Surfaces]
- This product will not leave grit or soap scum.
- This product will clean [,disinfect] and sanitize hard, non-porous surfaces, such items as {Insert from Use Sites section} and surfaces consisting of {insert from Surfaces section}²

SUBSTRATE CLAIMS:

- Cloth-like texture for scrubbing power
- textured for scrubbing power
- Cloths [Wipes] quickly remove dirt, spots and smudges
- Dual [action] [purpose] [scrubs] wipes]
- [Extra large] Sanitizing Towelettes
- Grooved for [Grime] [Tough Messes] [Grease]
- Improved scrubbing texture
- [Our] toughest substrate wipe ever
- Premoistened
- [Premoistened] [wet] disinfecting [textured] [antibacterial] [wipes] [towelettes] [cloths]
- Quilted Texture to [Scrub] [Power] [Fight] Through Tough Messes
- Textured to [Scrub] [Power] [Fight] Through Tough Messes
- 3-D Texture for Tough Messes
- [Strong] [Thick] wipe
- Strong wipe for tougher [jobs] [messes]
- Stronger Wipe Material
- [Textured cloth] gets up stubborn stuck on messes
- Textured [cloths] [towelettes] clean floors faster [and easier]
- Textured [Wipe] [cloth] [towelette] [for tough jobs] [for tough cleaning]
- Textured for better [cleaning] [scrubbing] power
- Textured to Pick Up Particles
- The wipe that is [strong] [durable] [thick] [heavy] enough to scrub [and] [clean]
- Thick [wipe], cloth-like texture
- Thicker
- Thicker than an ordinary wipe
- Thicker, cloth-like feel for tough messes
- Tough like a towel
- Tough Textured Wipes
- [Tough] [Thick] wipe[s] for tough messes
- Tough[er] wipe for tough[er] cleaning [jobs]
- [Thick] [Quilted] Texture for Tough Cleaning
- With a cloth-like 3D texture

PACKAGING CLAIMS:

- Better [package] [dispensing]
- Breakthrough package
- [Convenient] [Hassle-free] [One-hand] dispensing
- Dispenses better
- Dispenses Like A Tissue [Tough Like A Cloth [Towel]]
- Dispenses like a tissue, cleans like a cloth
- Easier dispensing
- Easy [dispensing] [Glide Lid]
- Easy dispense [lid] [package]
- Easy dispensing [and] [tough texture] [for the ultimate wipes experience]
- [Easy] [EZ] start
- Easy to [open] [thread] [access lid] [dispense]
- Easy to use
- Easy-glide dispensing top
- Fewer rips, bunches, and snags
- [Just like a tissue box] [Tissue box dispensing]
- Just [pull] [pop] wipe and toss.
- Less [Oil Consumption], [Landfill Waste], [Production Energy], [and] [Freight Energy]
- No [more] [pinched fingers] [rips] [tears]
- One at a time [dispensing, like a tissue box]
- One wipe at a time dispensing
- Only use approved refill packs.
- Package breakthrough
- Pop up
- Pop and go
- Pop and Clean
- Portable
- Produced with [Wind] [Solar] Energy
- Recyclable packaging
- [Regular] [and] [Everyday] Wipe Pack
- Specially designed package that easily dispenses one at a time

{Note to reviewer: The following may only be used if the Supplemental Registrant has documentation to support these claims.}

- [30%] [xx%] Thicker and Quilted Texture [for Tough] [Messes] [Cleaning]
- [30%] thicker wipes
- 100% Cotton Wipe fabric
- [Made with] [xx%] less plastic
- [Made with] [xx%]less plastic [than similar size containers][than previous[ly] used container[s]]
- Package contains xx% recycled materials
- Package contains xx% post-consumer waste
- Package is 100% recyclable
- Packaged with 100% [xx%] [wind] [solar] energy
- Packaging contains xx% [post-consumer waste] [recycled materials]
- [Substrate] [Wipe] [Towelette] [Cloth] composed of 100% [xx%] recycled materials
- [Substrate] [Wipe] [Towelette] [Cloth] composed of 100% [xx%] renewable materials
- [Substrate] [Wipe] [Towelette] [Cloth] [material] derived 100% from [wood pulp] [cotton] [cellulose] [recycled cellulose]
- [[The][This] product was] [Produced] [Manufactured] with [100%] [xx%] [wind] [solar] energy
- Wipe fabric made from 100% renewable resources

OTHER CLAIMS:

- {bac-te-ri-o-stat-ic} Noun 'To inhibit the further growth of odor causing bacteria'
- For full [bacteriostatic] effectiveness of BioSpear, allow surface to dry completely
- Bio-Spear Sanitizing Towelettes are non-woven disposable towelettes pre-saturated with Bio-Spear.
- We've Got You Covered
- [Made] [Manufactured] in the USA [with Domestic and Imported Ingredients]
- Safe for use on the following surfaces: {Insert from Surfaces section}
- Will not damage the following surfaces: {Insert from Surfaces section}

- Call (Insert phone number)
- Comments?

- Fragrance-free

FOOTNOTES:

¹ if not removed from surface[s]

² when used as directed

{Reviewer Note: The following graphics are optional. They will be affixed to the label/canister so that it does not interfere with any label text.}



{Note to reviewer: The following is considered optional marketing language. Each item below also represents a graphic depicting the corresponding area of use. The graphics will only represent individual objects or outsides or insides of buildings as described below. No people, animal, or food will be depicted in graphics.}





Stainless Steel



Glass



Painted Surfaces



Electronics



Do not use as a baby wipe



Do not flush

[

Emerging Viral Pathogens 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

For an emerging viral pathogen that is a/an...	...following the directions for use for the following supporting organism(s) on the label
Enveloped virus	Adenovirus (ATCC VR-5) (Strain Adenoid 75)

[Product Name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, nonporous surfaces. Therefore, [Product Name] can be used against [name of emerging virus] when used in accordance with the directions for use against Adenovirus (ATCC VR-5) (Strain Adenoid 75) 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 Adenovirus (ATCC VR-5) (Strain Adenoid 75) on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.

]