

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 19, 2021

Brian Hogan Agent, KRK Consulting, LLC Spraying Systems Company 16815 Southpark Drive Westfield, IN 46074

Subject: PRIA Label Amendment – Application to Add Additional Public Health

Organisms and Corresponding Label Claims.

Product Name: "Pathonex"

EPA Registration Number: 88161-1 Received Date: March 3, 2021

Action Case Number/Decision Number: 00293717

Dear Mr. Hogan:

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. 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.

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) lists 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 Assurance.

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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, please contact Michael Varco by phone at (202) 566-0667, or via email at Varco.Michael@epa.gov.

Sincerely,

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

Enclosure

# **Pathonex**

(Hypochlorous Acid Solution)

(Ready to Use) (One-Step Disinfectant<sup>3</sup>), (Hospital Broad-Spectrum Disinfectant<sup>2</sup>), (Deodorizer), ((One-Step) Fungicide<sup>3</sup>), ((One-Step<sup>3</sup>) Viricide<sup>2</sup>), (and) (Food Contact Surface Sanitizer<sup>1</sup>)

Pathonex has efficacy against [any target pathogen listed in table 1,2, and 3] in [respective contact time] on [any use site on list 1&2 ] (and/or) [any use surface in list 3&4]. Effective against odor-causing bacteria on [any use site on list 1&2] (and/or) [any use surface on list 3&4].

Active Ingredient: Hypochlorous Acid	00.0181%
Inert Ingredients: Water	<u>99.9819%</u>
Total	100.0000%

Contains 180 ppm Free Available Chlorine (FAC)

ACCEPTED

11/19/2021

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 88161-1

# **Keep Out of Reach of Children**

Product must be used within 30 days of production (,or use chlorine test strips to quantify the available chlorine. Do not use if less than 162 ppm free available chlorine (FAC).)

Use By:			
Lot Number:			

(See reference sheet (enclosed in each case) for (a complete list of organisms) (additional (features) (claims) (directions for use)) (for this product).) [Appendix A, B, C]

Manufactured by: Spraying Systems Co. 100 W. Lake Dr. Glendale Heights, IL 60139

EPA Registration No.: 88161-1 EPA Est.: 88161-IL-002

Net Contents: (As Specified in X gal, X oz, X L, or X mL (X is a placeholder for 1-300))

[Note to reviewer: net Contents to be displayed on the front page of the label]



# Directions for Use (Sanitization)<sup>1</sup>

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

((Pathonex (This product)) can be used on hard, nonporous surfaces in commercial -and/or- household premises (including [any use site listed below in list 1, 2&3]) -and/or- eating establishments.)

### To Sanitize (and Deodorize) Hard, Non-Porous Food Contact Surfaces:

- 1. Remove visible soil. Thoroughly pre-clean surface (with) (PathoClean®), (Pathopure), (Klarion® Cleaner), (or other cleaning solution) prior to sanitizing.
- 2. Apply (spray, wipe or soak) Pathonex (with) (cloth), (sponge) (or) (sprayer) onto the pre-cleaned surface until thoroughly wet.
- 3. Allow surfaces to remain visibly wet for a contact time of (one) (-or-) (1) minute.
- 4. (If desired) air dry or wipe dry. (Must) (rinse) (and/or) (wipe) (dry on metal surfaces).

### To Sanitize (and Deodorize) Conveyors, Peelers, Slicers and Saws for Food Processing:

- 1. Remove visible soil by spraying or wiping all surfaces of equipment with water.
- 2. Thoroughly pre-clean surface (with) (PathoClean®), (Pathopure), (Klarion® Cleaner), (or other) (cleaning solution) prior to sanitizing.
- 3. Apply (spray, wipe or soak) Pathonex (with) (cloth), (sponge) (or) (sprayer) onto the pre-cleaned surface until visibly wet.
- 4. Allow surfaces to remain visibly wet for a contact time of (one) (-or-) (1) minute.
- 5. (If desired) air dry or wipe dry. (Must) (rinse (and/or) (wipe dry) on metal surfaces).

### To Sanitize (and Deodorize) Holding Tanks:

- 1. Remove visible soil by spraying fresh water, preferably with a tank cleaning device, until all surfaces have been covered.
- 2. Thoroughly pre-clean surface with (PathoClean®), (Pathopure), (Klarion® Cleaner), (or other) (cleaning solution) prior to sanitizing (preferably through a tank cleaning device).
- 3. Apply Pathonex to all surfaces (, preferably with a tank cleaning device,) until all surfaces have remained visibly wet for a contact time of (one) (-or-) (1) minute.
- 4. (If desired) (air dry or wipe dry). (Must) (rinse) (and/or) (wipe) (dry on metal surfaces).

### To Sanitize (and Deodorize) Process (and/or CIP) Lines:

- 1. Clear the line of visible soil and flush out any visible soil with fresh water.
- 2. Continuously flush (PathoClean®), (Pathopure), (Klarion® Cleaner), (or other) (cleaning solution) through process or plumbing lines until surfaces are clean.
- 3. Continuously flush Pathonex through process or plumbing lines until all surfaces have remained visibly wet for (one) (-or-) (1) minute contact time.
- 4. Continuously flush lines with fresh water until all Pathonex has been purged from the process or plumbing lines.

# Directions for Use (Disinfection)<sup>2</sup>

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

((Pathonex (This product)) can be used on hard, nonporous surfaces in commercial -and/or- institutional - and/or- hospital -and/or- household premises (including [any use site listed below in list 1&2]) -and/or- eating establishments -and/or- veterinary premises.)

((For use in)(Commercial)(,industrial)(,retail)(,institutional)(,healthcare)(, residential properties)(-and/or-)([any use site listed below in list 1&2]).)

### To Disinfect specifically against SARS-CoV-2 virus on Hard, Non-Porous Surfaces:

- 1. Remove visible soil and thoroughly pre-clean surface (with) (PathoClean®), (Pathopure), (Klarion® Cleaner), (or other) (cleaning) (solution) prior to disinfection.
- 2. Apply (spray, wipe or soak) Pathonex (with) (cloth), (sponge) (or) (sprayer) onto the pre-cleaned surface until thoroughly wet.
- 3. Allow surfaces to remain visibly wet for a contact time of (one) (-or-) (1) minute.
- 4. (If desired) (air dry or wipe dry). (Must) (rinse (and/or) (wipe dry) on metal surfaces).

### To Disinfect (and Deodorize) Hard, Non-Porous Surfaces:

- 1. Remove visible soil and thoroughly pre-clean surface (with) (PathoClean®), (Pathopure), (Klarion® Cleaner), (or other) (cleaning) (solution) prior to disinfection.
- 2. Apply (spray, wipe or soak) Pathonex (with) (cloth), (sponge) (or) (sprayer) onto the pre-cleaned surface until thoroughly wet.
- 3. Allow surfaces to remain visibly wet for a contact time of (ten) (-or-) (10) minutes.
- 4. (If desired) (air dry or wipe dry). (Must) (rinse (and/or) (wipe dry) on metal surfaces).

### To Disinfect (and Deodorize) Non-Critical Medical Equipment and Surfaces:

- 1. Thoroughly pre-clean surfaces (with) (PathoClean®), (Pathopure), (Klarion® Cleaner), (or other) (cleaning) (solution) prior to disinfection.
- 2. Apply (spray, wipe or soak) Pathonex directly to pre-cleaned surfaces. Thoroughly wet the area to be disinfected.
- 3. Allow surfaces to remain visibly wet for a contact time of (ten) (-or-) (10) minutes.
- 4. (If desired) (air dry or wipe dry). (Must) (rinse) (and/or) (wipe) (dry on metal surfaces).

The 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.

# Directions for Use (One-Step Disinfection)<sup>3</sup>

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

((Pathonex) (This product) can be used as a one-step disinfectant<sup>3</sup> (and) (deodorant)(odor neutralizer) capable of cleaning, (and) disinfecting (deodorizing) hard, non-porous surfaces (in commercial (-and/or- institutional) (-and/or- hospital) (-and/or- household premises (including [any use site listed below in list 1&2])) (-and/or- eating establishments) (-and/or- veterinary premises).))

### (To)(For) One-step Clean(ing) Disinfect(ion) (and Deodoriz(e)(ing)) (of) Hard, Non-Porous Surfaces:

- 1. Remove visible soil (if needed).
- 2. Apply (spray, wipe or soak) Pathonex (with) (cloth,) (sponge) (or) (sprayer) onto the surface until thoroughly wet.
- 3. Allow surfaces to remain visibly wet for a contact time of (ten) (-or-) (10) minutes.
- 4. (If desired) (air dry or wipe dry). (Must) (rinse) (and/or) (wipe) (dry on metal surfaces).

# (To)(For) One-step Clean(ing) Disinfect(ion) (and Deodoriz(e)(ing)) (of) Non-Critical Medical Equipment and Surfaces:

- 1. Remove large soil particulate (if needed).
- 2. Apply [spray, wipe or soak) Pathonex directly to pre-cleaned surfaces. Thoroughly wet the area to be disinfected.
- 3. Allow a contact time of (ten) (-or-) (10) minutes.
- 4. (If desired) wipe surface dry using a clean disposable cloth (and/or towel). Discard cloth (and/or towel).

The 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.

# **Directions for Use**

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

((Pathonex) (This product) has been tested and found to be effective against the following micro-organisms on a pre-cleaned, hard, non-porous surface.)

Target Pathogens for Food Contact Surface Sanitization <sup>1</sup>	Strain	Contact Time
Salmonella Enterica	ATCC 6539	1 minute
Staphylococcus Aureus	ATCC 6538	1 minute

Target Pathogens for Disinfection <sup>2</sup>	Strain	Contact Time
SARS-Related Coronavirus 2	Isolate USA- WA1/2020	1 minute
Poliovirus type 1	ATCC VR-1562	
Feline Calicivirus (Norovirus surrogate)	ATCC VR-782	
Human Immunodeficiency virus type 1 (HIV-1)	HTLV-IIIB	
Influenza A (H1N1) virus	ATCC VR-1469	
H1N1 Influenza A virus (H1N1)	CDC#2009712192	
Herpes simplex virus type 2	ATCC VR-734	
Avian Influenza A (H7N9) virus	CDC#2013759189	
Trichophyton interdigitale	ATCC 9533	
Salmonella enterica	ATCC 10708	10 minutes
Staphylococcus aureus	ATCC 15442	
Pseudomonas aeruginosa	ATCC 6538	
Listeria monocytogenes	ATCC 19117	
Burkholderia cepacia	ATCC 25416	
Methicillin Resistant Staphylococcus aureus - MRSA	ATCC 33592	
Vancomycin Resistant Enterococcus faecalis - VRE	ATCC 51575	
New Delhi metallo-beta-lactamase 1 (NDM-1) producing Klebsiella pneumoniae	CDC#1000527	
Escherichia coli	ATCC 11229	

### **Directions for Use**

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

((Pathonex) (This product) has been tested and found to be effective against the following micro-organisms in the presence of a 5% soil load on a hard, non-porous surface.)

Target Pathogens for One-Step Disinfection <sup>3</sup>	Strain	<b>Contact Time</b>	
SARS-Related Coronavirus 2	Isolate USA- WA1/2020		
Poliovirus type 1	ATCC VR-1562		
Feline Calicivirus (Norovirus surrogate)	ATCC VR-782		
Human Immunodeficiency virus type 1 (HIV-1)	HTLV-IIIB		
Influenza A (H1N1) virus	ATCC VR-1469		
H1N1 Influenza A virus (H1N1)	CDC#2009712192		
Herpes simplex virus type 2	ATCC VR-734	10 minutes	
Avian Influenza A (H7N9) virus	CDC#2013759189		
Trichophyton mentagrophytes	ATCC 9533		
Burkholderia cepacia	ATCC 25416		
Methicillin Resistant Staphylococcus aureus - MRSA	ATCC 33592		
Vancomycin Resistant Enterococcus faecalis - VRE	ATCC 51575		
New Delhi metallo-beta-lactamase 1 (NDM-1) producing Klebsiella pneumoniae	CDC#1000527		
Escherichia coli	ATCC 11229		

# Special Instructions for Cleaning and Decontamination against HIV on Surfaces/Objects Soiled with Blood/Body Fluids.

Personal Protection: When handling items soiled with blood or body fluids, wear personal protection such as disposable latex gloves, gowns, masks, and eye coverings.

Cleaning Procedures: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of (Pathonex) disinfectant. Contact Time: thoroughly wet surface with Pathonex for 10 minutes. Then rinse or wipe clean.

Disposal of Infectious Materials: Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal.

## (Helpful) Household Tips – or – (Helpful) Consumer Hints

[Note to reviewer: When appropriate the corresponding approved icons from Appendix A can be used with the following "Tips or Hints" section.]

# (Keep SARS-CoV-2 (the virus that causes COVID 19) off (high-touch) hard, non-porous surfaces (and/or) (hard, non-porous electronic surfaces (like your phone))

Thoroughly preclean the surface, spray on or wipe on Pathonex until the surface is visibly wet (be sure to not get liquid into electronics only on the hard, non-porous surfaces). Allow surface to remain visibly wet for 1 min(ute). Wipe or air dry.)

### Clean(ing) Flowerpots and Planters

Cleaning flower containers helps prevent the transfer of molds and diseases from old plants to new ones. Wash and (thoroughly) rinse pots and planters. Soak 10 min(utes) in a (solution-or-Pathonex), then rinse.)

### **Deodorizing Cat's Litter Box**

Unpleasant cat box odors can be eliminated when this product is used to kill odor-causing germs. Wash litter box with sudsy water and rinse. Then wet the surfaces with Pathonex. Let solution stand 10 min(utes) before rinsing (if desired))

### (Disinfect(ing) (Pet Areas) (-and/or-) (Nonporous Toys) (-and/or-) (Accessories)

(This product) (-or -) (Pathonex) can disinfect your pet areas -and/or- nonporous toys -and/or- accessories. Thoroughly (pre-)clean surface, soak or wipe with Pathonex. Allow surface to remain visibly wet for at least 10 min(utes). Wipe or air dry.

### Eliminating Garbage Can -and/or- Diaper Pail Odors

(This product) (-or-)(Pathonex) can deodorize and sanitize your garbage cans -and/or- diaper pail by eliminating the bacteria that cause odors. Wash garbage cans-and/or- diaper pail with (soapy water) (pathopure) (or other cleaning solution) and rinse. Then to deodorize and sanitize: spray Pathonex over the inside of the can. Visibly wet the surface. Let the solution stand 1 min(ute) before rinsing. To disinfect: Let the solution stand 10 min(utes) before rinsing.)

### **Eliminating Refrigerator Odors**

This product kills odor causing bacteria and leaves your refrigerator smelling fresh and clean. Use it inside and out. Remove food before using this product, and allow surfaces to come to room temperature. Thoroughly preclean surfaces (with cleaning solution -or- pathopure). Apply Pathonex to the surface until visibly wet. To sanitize allow the solution to

stand 1 min(ute). To disinfect allow solution to stand 10 min(utes). Rinse and then (air-or-wipe) dry interior surfaces a few min(utes) before replacing food.)

### Kitchen and Bathroom

Clean, disinfect and deodorize sinks, countertops, bathtubs, showers, floors, vinyl and glazed tile.

- 1) Wash, wipe or rinse items with (cleaning solutions) (, Pathopure) (,and/or)(water).
- 2) Apply (Pathonex -or- disinfecting solution -or this product) until visibly wet.
- 3) Let surface remain visibly wet for 10 min(utes) before rinsing.
- 4) Rinse, wipe or air dry.

### Sanitizing (Kitchen Wares)(Pots & Pans, Glasses, Dishes, utensils) in a Three (3) Basin Sink

Clean all kitchen wares in the first basin with warm water and (cleaning solution -or- Pathopure), rinse wares in the second bason, immerse wares in Pathonex in the third basin for 1 minute. Drain and dry.

### **Removing Exterior Mold Stains**

Mold stains on colorfast exterior surfaces of your home, like siding, tile roofs, sealed brick, stucco and patio stone can be easily removed using this product. First, (hose -or- spray -or- wash) surfaces to remove loose soil. Then apply Pathonex to surfaces until visibly wet. Reapply the solution as needed to keep the area wet for 10 min(utes). Rinse thoroughly to remove residue. (Avoid applying solution in direct sunlight or to unfinished wood.) (Avoid prolonged contact with metals if contact is made rinse thoroughly.)

### Removing Mold and Mildew

(Mold and mildew in the bathroom can be removed easily and effectively using this product.) Simply wipe down surfaces using Pathonex. Keep surface wet 10 min(utes); then rinse thoroughly and wipe dry.

### **Removing Patio Moss and Mildew Stains**

Patio moss and mildew stains can be unsightly, slippery and dangerous. (Hose -or- Spray -or- Wash) patio to remove loose debris. Then remove moss and mildew stains by washing the area with Pathonex. Reapply the solution as needed to keep the area wet for 10 min(utes). Brush (or scrub) as needed to remove moss and then rinse thoroughly. (Not for use on (painted) wood.) Avoid excessive runoff near plants.

### (To) Sanitize -or- Sanitizing and Remove -or- Removing Stains from Kitchenware

Tough stains can be removed from china, dinnerware, dishes, plastic and glassware with this product. Plus, this product sanitizes as it cleans. Wash items thoroughly as you normally would. Then soak for 1 min(ute) in Pathonex. Finally, rinse, drain and air dry.

### Sanitize -or- Sanitizing Pet's Food and Water Bowls -or- Pet Bowl

To sanitize pet food containers, wash bowls with (pathopure -or cleaning solution) and rinse. Fill bowls with Pathonex (or spray with Pathonex until visibly wet). Let stand 1 min(ute), drain, rinse and air dry.

### **Sanitizing Baby Items**

Baby bottles and dishes can be easily sanitized using this product. Soak washed items for 1 min(ute) in Pathonex; then drain and rinse dry.

# **Storage and Disposal**

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

**Pesticide Storage:** Store in a closed plastic container in a cool, dry location away from heat and sunlight. Do not shake. Do not store near easily oxidizable materials, acids and reducers. In case of spill, isolate container (if possible) and flood area with water to dissolve all material before disposing this container in trash.

**Emergency Handling:** In case of contamination or decomposition, do not reseal container. Isolate in open, well-ventilated area. Flood with large amounts of water. Cool unopened containers in vicinity by water spray.

**Pesticide Disposal:** Pesticide wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility. Improper disposal of excess pesticide, spray mixture or rinsate is violation of Federal law. If these wastes cannot be disposed of according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the U.S. EPA Regional Office for guidance.

**Container Handling:** [Note to reviewer: One of the following paragraphs will be used on labels for refillable containers:]

(For refillable containers less than or equal to 5 gallons)

Refillable container. Refill this container with Pathonex only. Do not reuse this container for any other purpose. Cleaning the container before refilling or final disposal is the responsibility of the person refilling or disposing of the container. To clean the container before final disposal, empty the remaining contents into application equipment or a mix tank. Fill container about 10 percent full of water. Agitate vigorously or recirculate water with pump for two (2) minutes. Dispose of rinsate as pesticide waste. Repeat the rinsing procedure two (2) more times. Then offer for recycling if available or puncture and dispose of in sanitary landfill, or by incineration, or by procedures allowed by state and local authorities.

(For refillable containers greater than 5 gallons) [Note to reviewer: Only one of the following paragraphs will be used on containers greater than 5 gallons.]

Refillable container. Refill this container with Pathonex only. Do not reuse this container for any other purpose. Cleaning the container before refilling or final disposal is the responsibility of the person refilling or disposing of the container. Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ½ full with water and replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for at least 30 seconds. Stand the container on its end and tip it back and forth several times. Dispose of rinsate in accordance with proper pesticide disposal. Repeat this procedure two more times. Offer container for reconditioning, if appropriate.

-OR-

Refillable container. Clean container promptly after emptying. Pressure rinse as follows: Empty the remaining contents into application equipment or a mix tank and continue to drain for 10 seconds after the flow begins to drip. Insert pressure-rinsing nozzle in the side of the container, and rinse at about 40 PSI for at least 30 seconds. Drain for 10 seconds after the flow begins to drip. Offer for reconditioning, if appropriate.

# **Physical or Chemical Hazards**

**Pathonex** is not compatible with other chemicals such as acids, ammonia and hydrogen peroxide. DO NOT MIX WITH OTHER CHEMICALS. (**Pathonex** is an electrolytic activated aqueous solution produced by separating the ions of a brine solution through selectively permeable membranes changing the properties of the water into an oxidizing agent exhibiting antimicrobial properties). **Pathonex** is produced at a near 5.5 pH where the predominant antimicrobial agent is hypochlorous acid, an efficient and efficacious species of chlorine. Hypochlorous acid kills bacteria according to label directions. **Pathonex** can be applied as a liquid or spray. (**Pathonex** freezes at 32° F and boils at 212° F.) **Pathonex** is a colorless, aqueous solution, with a slight chlorine or ozone odor. After production, **Pathonex** must be stored in a closed, plastic container in a cool, dark area away from direct sunlight. The **Pathonex** product must be used within 30 days of production.

### **Additional Use Sites [List 1]:**

- + Business(es)
- + Bar(s)
- + Taverns
- + Breweries
- + Pool Halls
- + Cafeteria(s)
- + Coffee shop(s)
- + Commercial building(s)
- + Convenience store(s)
- + Facility (facilities)
- + Food processing facility (facilities)
- + Produce area(s)
- + Seafood warehousing and/or fishery (fisheries)
- + Food service facility (facilities)
- + Food serving area(s)
- + Food cart(s) and/or food truck(s)
- + Fast food restaurant(s)
- + Shop(s)
- + Restaurant(s), bar(s)
- + Beverage shop(s) and brewery (breweries)
- + Delicatessen(s)
- + Supermarket(s)
- + Grocery store(s)
- + Cooperative market(s) and/or Co-op(s)
- + Mini-mart(s)
- + Convenience mart(s)
- + Liquor store(s)
- + Warehouse club(s)
- + Institution(al) facility (facilities)
- + Food preparation area(s)
- + Catering facility (facilities)
- + (Commercial)(institutional) kitchen(s) (and/or) (kitchenette(s)) (back-of-house) (front-of-house)
- + Commissary (Commissaries)
- + Banquet hall(s)
- + Dining area(s)
- + Hotel(s)
- + Motel(s)
- + Resort(s)
- + Hostel(s)
- + Bed and breakfast(s)
- + Casino(s)
- + Hospitality area(s)
- + Condominium(s)
- + Vacation home(s)
- + Apartment(s)
- + Dormitory (Dorm) (dormitories)
- + Lodging establishment(s)
- + Household(s)

- + Bathroom(s)
- (Bath)tub(s)
- + Home(s)
- + Mobile home(s)
- + Motor home(s)
- + Camper(s)
- + (General) facility (facilities)
- + Reception area(s)
- + Office(s) building(s)
- + Trans-warehousing
- + Warehouse(s)
- + Distribution center(s)
- + Shipping facility (facilities)
- + School(s)
- + Pre-school(s)
- + Elementary school(s)
- + Middle school(s)
- + High school(s)
- + Preparatory school(s)
- + Alternative school(s)
- + College(s)
- + Vocational school(s)
- + University (universities)
- + Arena(s) and/or sports stadium(s)
- + Athletic facility (facilities)
- + Workout facility (facilities)
- + Fitness center(s)
- + Health club(s)
- + Gym(nasium)(s)
- + Locker room(s)
- + Yoga Studios
- + Martial art facilities / Dojos
- + Recreation(al) center(s)
- + Bowling alley(s)
- + Gaming facility (facilities)
- + Public recreation(al) facility (facilities)
- + Amusement park(s) and/or theme park(s)
- + Movie theatre(s)
- + Indoor playground(s)
- + Club(s)
- + (Exterior) surfaces of fountain(s)
- + Convocation center(s)
- + Airport(s)
- + Church (facility) (facilities)
- + Food pantry (pantries)

### Additional Use Sites [List 2]:

- + Charitable establishment(s)
- + Government facility (facilities)
- + Public venue(es)
- + Police station(s)
- + Fire station(s)
- + Post office(s)
- + Library (libraries)
- + Customs facility (facilities)
- + Immigration(s) facility (facilities)
- Military installation(s) and/or accommodation(s) and/or barrack(s)
- + Correctional facility (facilities)
- + Prison(s)
- + Childcare center(s)
- + Day-care center(s)
- + Mall(s)
- + Shopping center(s)
- + Retail outlet(s)
- + Wholesale outlet(s)
- + Mass merchandiser(s)
- + Discount retailer(s)
- + General merchandise store(s)
- + Pet store(s)
- + Laboratory (laboratories)
- + Cruise ship(s) and/or ship(s) and/or boat(s) and/or yacht(s)
- + Shipyard(s)
- + Airplane(s) and/or airport(s)
- + Train(s)
- + Transportation terminal(s) and/or transportation equipment and/or transportation vehicle(s)
- $+ \quad Subway(s) \ and/or \ subway \ car(s)$
- + Trolley(s) and/or tram(s) and/or streetcar(s)
- + Truck(s)
- + Bus(es)
- + Taxi(s)
- + Limo(s)

- + Vehicle(s) and/or automobile(s)
- + Emergency vehicle(s)
- + Transport container(s)
- + (Parcel) transport vehicle(s) and/or semitrailer(s)
- + Park(s) and/or park facility (facilities)
- + Truck stop(s)
- + Rest area(s)
- + Shelter(s)
- + Playground(s)
- + Trailer(s) and/or camper(s)
- + Flower shop(s) and/or florist(s)
- + Humane shelter(s) or animal shelter(s)
- + Pet care facility (facilities) or grooming facility (facilities) or kennel(s)
- + Veterinary facility (facilities)
- + Zoo(s) and/or animal sanctuary (sanctuaries)
- + (Animal) transport(ation) vehicle(s)
- + Storage facility (facilities) and/or storage area(s)
- Long-term care facility (facilities) and/or rehabilitation facility (facilities) and/or therapy facility (facilities)
- + Recycling center(s)
- Healthcare facility (facilities) and/or hospital(s)
- + Senior living facilities
- + (Hair) (and/or) (Nail) Salons
- + Barber Shops
- + Spa(s)
- + Dentist Offices
- + Hospitals
- + Doctor Offices
- + Clinics
- + Casinos
- + Hookah Bars / Smoke Shops
- + Game shops

### Hard Nonporous Use Surfaces [List 3]:

- + Animal equipment and/or animal cage(s) and/or feed rack(s)
- + Appliance exterior surface(s)
- + Booster seat(s)
- + Cabinet(s)
- + Casino machine(s)
- + Cellular phone(s)
- + Chiller(s)
- + Computer keyboard(s)
- + Computer monitor(s)
- + Counter(s) and/or countertop(s)
- + Crib(s)
- + Desk(s)
- + Dish(es)
- + Dish rack(s)
- + Door(s)
- + Doorknob(s)
- + Drain board(s)
- + Faucet(s)
- + Fixture(s)
- + Floor(s)
- + Food cart(s) and/or food truck(s)
- + Food case(s) (exterior)
- + Food tray(s)
- + Freezer surface(s)\*
- + Furniture (test on inconspicuous spot first)
- + Game machine(s)
- + Garbage can(s) and/or trash can(s)
- + Glass (and/or) (mirror(s))
- + Grocery (store) cart(s) and/or supermarket cart(s)
- + Hamper(s)
- + Hand (soap) dispenser(s)
- + Handrail(s)
- + Hard (non-porous) surface(s)
- + Headset(s)
- + Highchair(s)
- + High touch surface(s) (points)
- + (Exhaust) hood(s)
- + Microwave surface(s)
- + Oven surface(s)\*
- + Other telecommunication equipment
- + Play table(s) and/or station(s)

- + Pot(s) and/or pan(s) and/or ware
- + Reception counters and/or area(s)
- + Refrigerator surface(s)\*
- + Shelve(s) and/or shelving
- + Sink(s)
- + Table(s)
- + Telephone(s)
- + Sealed tile and/or grout
- + Towel dispenser(s)
- + Toy(s)
- + Salad bar splash and/or sneeze guard(s)
- + Storage container(s)
- + Utensil(s)
- + Vanity (vanities) and/or vanity top(s)
- Ware washer(s) and/or ware wash machine(s) and/or dishwasher(s) and/or dish machine(s)
- + (Wash) basin(s)
- + (Washable) chair(s)
- + (Washable) wall(s)
- + (Water) (drinking) fountain(s)
- + Wheelchair(s)
- + Window(s) (and/or) (glass) (and/or) (mirror(s))
- + Sports equipment
- + Non-porous cutting boards
- + (Dishes) (and/or) (utensil(s))
- + Counters
- + Cookware
- + Carts
- + Exercise equipment
- + Dumbbells
- + Weights
- + Weight bars
- + Benches
- + Vinyl floors
- + Walkers
- + Scales
- + (Non-critical Medial)(Dental)(Veterinary) tools
- + (Computer)(electronic) Mice
- + Remote control (and/or) (Joy sticks)
- \* surfaces must come to room temperature for treatment

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### **Surface Materials [List 4]:**

- + ABS (Acrylonitrile butadiene styrene) (plastic)
- + Aluminum
- + Baked enamel
- + (Brushed) (polished) nickel
- + (Brushed) bronze
- + Chrome
- + Common hard, non-porous household (environmental surfaces)
- + Formica
- + Glass(ware)
- + (Glazed -or- Sealed) (ceramic) tile
- + (Glazed -or- Sealed) concrete
- + (Glazed -or- Sealed) porcelain
- + (Glazed -or- Sealed) porcelain enamel
- + Sealed granite
- + (Hard,) (non-porous) surface(s) or environmental surface(s)
- + Laminated surface(s)
- + Sealed limestone
- + Linoleum

- + Sealed Marble
- + Melamine
- + Mirror
- + Painted surface(s)
- + Plastic laminate(s)
- + (Polished) chrome
- + Polyacrylic
- + Polycarbonate
- + Polyethylene
- + Plastic
- + Sealed slate
- + Stainless steel
- + Sealed stone surface(s)
- + Synthetic marble
- + (Glazed -or- Sealed) terrazzo
- + Vinyl tile
- + Washable walls
- + Washable Floors
- + Sealed wood

[Note to reviewer: Must specify glazed or sealed cannot omit entirely]

# **Emerging Viral Pathogen Claims**

(Note to Reviewer: None of the language in this section is to appear on any final printed label)

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 when used in accordance with the directions for use for the following organisms on the label:

For an emerging viral pathogen that is a/an	follow the directions for use for the following organisms on the label:
Enveloped virus	One of the following: Poliovirus type 1, ATCC VR-1562, Strain Chat
Large Non-enveloped	One of the following: Poliovirus type 1, ATCC VR-1562, Strain Chat
Small, non-enveloped virus	<b>Two</b> of the following: Poliovirus type 1, ATCC VR-1562, Strain Chat Feline Calicivirus as a surrogate for Norovirus

Table revision made: 10/08/2020

The following statements may be used only in non-label communications as described in EPA's Emerging Viral Pathogens guidance, and only under the conditions outlined in that guidance:

- Pathonex has demonstrated effectiveness against viruses similar to [emerging viral pathogen) on hard, non-porous surfaces. Therefore, Pathonex can be used against [emerging viral pathogen) when used in accordance with the directions for use against [name of supporting virus(es)) on precleaned, 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). Pathonex 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 and Norovirus on hard, non-porous surfaces. Refer to the [CDC or OIE) website at [website address) for additional information.

### **Optional Marketing Language/Additional Claims:**

### (General Claims)

- + Produced by the electrolysis of salt (NaCl) and water (H2O)
- + Electrochemically activated solution (ECAS)
- + (This product is an)(Pathonex is an) electrolytically generated sanitizer/disinfectant
- + Brine does not enter (the) (electrolytic) cell
- + Made from water, salt and electricity
- + Converts water and salt into a disinfectant using electricity
- + No salt residue
- + (Patented) (technology where) salt (NaCl) does not enter the (electrolytic) cell and therefore (is) not added to (the) output solution(s)
- + (Generated using) (PathoSans®) patented (electrolytic) cell technology
- + (This product is) (generated using) (PathoSans) patented (electrolytic) cell technology(.) (keeps (or keeping) the brine separate(d) from the (product) output solution)
- + pH is between 4.5 and 6 (which is the optimal range for (hypochlorous acid) stability)
- + Hypochlorous (acid) is an oxidizing agent with antimicrobial activity
- + (A) (dilute) hypochlorous acid solution
- + Freezing point: 32°F
- + Boiling point: 212°F
- + Ready-to-use (and/or) (no dilution required)
- + No mixing (necessary)
- + No complicated dilution process(es)
- + Drain (and disposal) friendly
- + Kills 99.9% of germs $^{1(,2)(,3)}$ , compatible with (surfaces [any on list 3 & 4] -and/or- the environment)
- + Do more with less! (Only 0.0181% active (and 99.9819% water) with proven results<sup>1,2,3</sup>)(Proven (results)(disinfection<sup>2,3</sup> (and/or) (sanitization<sup>1</sup>)) with less than 0.02% active)
- + Family-friendly way to disinfect
- + Gentle on most hard, non-porous surfaces
- + (This product) rapidly breaks down after use
- + (This product is) not harmful to septic (and wastewater treatment) systems
- + Refillable container
- + (No need for)(Use without) gloves
- + Hospital disinfectant (,virucide) (and/or fungicide) that can still be used (on food contact surfaces) (-or-) (food establishments).
- + Gentle enough to (sanitize) (and/or) (disinfect) (homes) (nurseries) (playrooms)
- + A (gentle) (mild) way to sanitize (and/or disinfect)

- + Affordable
- + Easy to use
- + Convenient
- + Simple
- + Economical
- + Consistent
- + Proven to (sanitize and/or disinfect) at 180 ppm of (free active chlorine) (FAC)
- + Pathonex is a clear liquid with a slight chorine smell
- + Can be stored up to 30 days and still sanitize (and/or disinfect)
- + (Can) reduce cross-contamination between treated surfaces
- + No rinsing necessary
- + Will not leave grit or soap scum
- + (Removes)(Prevents) hard water buildup (or deposit)
- + (0%) (none) (No) (free from) (unnecessary ingredients) (ammonia) ((synthetic) (artificial) fragrance(s)) (fragrance) (dyes) (fragrance(s) and dye(s)) (rinse required) (parabens) (artificial coloring) (mineral oil) (triclosan) (Perchloroethylene) (hydrogen peroxide) (peroxide(s)) (peroxide bleach) (phosphates) (phosphates) (sodium hydroxide) (phthalates)
- + (This product) (Contains) no VOC (Volatile Organic Compounds)
- + (This product is) VOC (Volatile Organic Compounds) free
- + (This product) (Contains) no NPEs (Nonylphenol ethoxylates); Nonylphenol ethoxylate (NPE) free
- + (This product is) Phosphate free; Phosphate free
- + (This product is) Ammonia free; Ammonia free
- + (This product is) Alcohol free; Alcohol free
- + (This product is) Phosphorous free; Phosphorous free
- + (This product) (contains) no phthalates; (This product is) phthalate free
- + (This product) (contains) no perchloroethylene; (This product is) perchloroethylene free
- + (This product) (contains) no triclosan; (This product is) triclosan free
- + (This product) (contains) no 2-butoxyethanol; (This product is) free of 2-butoxyethanol
- + (This product) (contains) no surfactants; (This product is) surfactant free
- + (This product) (contains) no chelating agents; (This product is) free of chelating-agents
- + (This product) (contains) no buffers; (This product is) free of buffers
- + (This product) (contains) no builders; (This product is) free of builders
- + (This product) (contains) no foaming agents; (This product is) free of foaming agents
- + (This product) (contains) no anti-foaming agents; (This product is) free of anti-foaming agents
- + (This product) (contains) no perfumes; (This product is) perfume free

- + (This product) (contains) no colorants (dyes); (This product is) free of colorants (dyes)
- + (This product) (contains) no additives; (This product is) additive-free
- + Allergen-free
- + For use on (insert one or more of the surfaces listed on the label)
- + For use in (insert one or more of use sites listed on label)
- + (Ideal) for use in kitchens (and public areas)
- + (For use on) high touch surfaces
- + For (daily) (everyday) use
- + For everyday disinfection
- + No (chemical(s)) (residue) (left) (behind)
- + No need to rinse
- + No-rinse
- + No accidental whitening
- + No rinsing (necessary) (required)

### (Antimicrobial Claims)

- + (Food contact surface) sanitizer<sup>1</sup> (disinfectant<sup>2</sup>) (one-step disinfectant<sup>3</sup>)
- + Antibacterial (action)
- + Bactericide
- + Bactericidal
- + Biocide
- + Biocidal
- + Disinfectant
- + Disinfecting
- + Disinfects
- + Deodorizes
- + Virucide\*\*
- + Virucidal\*\*
- + Fungicidal
- + (One-Step<sup>3</sup>) Fungicide
- + Sanitizes
- + Sanitizing
- + Inactivates viruses<sup>2,3</sup>
- + (Pathonex)(This product) (kills 99.9% germs<sup>2,3</sup>)((and/or) sanitizes<sup>1</sup>)((and/or)disinfects<sup>2,3</sup>) (in the [insert use site from list 1&2])
- + (Pathonex)(This product) kills 99.9% viruses<sup>2,3</sup> (in the [insert use site from list 1&2])
- + (Pathonex)(This product) kills the SARS-CoV-2 (virus)(COVID-19 virus) (that causes the COVID-19 disease) in (one) (1) minute\*

- + (Sanitizes) (kills) (eliminates) (destroys) (removes) 99.9% of (bacteria) (germs<sup>2,3</sup>) [insert any target pathogen listed<sup>1,2,3</sup>] (in your [insert any use site listed from list 1&2])
- + (Disinfects) (kills) (eliminates) (destroys) (removes) 99.9% of (bacteria) (germs<sup>2,3</sup>) [insert any target pathogen listed<sup>1,2,3</sup>] (in your [insert any use site listed from list 1&2])
- + Cost effective (food contact surface) sanitizer (and) ((hospital) disinfectant)
- + (Sanitize(s)) (Disinfect(s)) surfaces in food preparation (prep) areas
- + (Sanitize(s)) (Disinfect(s)) surfaces (in areas) where food may go
- + Tested according to AOAC test methods for (food-contact surface) sanitizer (and/or) (hospital disinfectant) (and/or) (viricide) (and/or) (fungicide)
- + Sanitize(s) (and/or) (disinfect(s))
- + Sanitizes surfaces (including [insert surfaces from list 1, 2, 3 & 4])
- + Disinfect surfaces (including [insert surfaces from list 1, 2, 3 & 4])
- + (Easy-to-use)(One-step) Disinfection<sup>3</sup>
- + Leaves surfaces (sanitized) (and/or) (disinfected)
- + Daily (sanitizing) (and/or) (disinfecting) of food-contact surfaces
- + Daily (cleaning) (and/or) (one-step) disinfection<sup>3</sup>
- + Sanitize(s) (and/or) (disinfect) glass (and/or mirror)
- + Food surface (contact) (sanitizer) (and/or) (Disinfectant)
- + (This product) leaves surfaces (sanitized)(and/or)(disinfected)
- + (Disinfects) (Sanitizes) hard, non-porous surfaces
- + Hospital disinfectant
- + Broad-spectrum disinfectant
- + 99.9% effective sanitation
- + 99.9% effective disinfection
- + Leaves (surfaces) sanitized (disinfected)
- + Deodorizes by killing common germs<sup>2,3</sup> (or bacteria<sup>2,3</sup> (and/or) viruses<sup>2,3</sup>)
- + Removes or eliminates odors (at the source) (by killing bacteria<sup>2,3</sup> (and/or) viruses<sup>2,3</sup>)
- + Eliminates (urine) odor
- + Eliminates odors (caused by bacteria)
- + Effective against odor causing bacteria
- + Removes odor causing bacteria, mold and mildew
- + Removes or eliminates odors (at the source)
- + For sanitizing (disinfecting) [insert one or more of the surfaces listed on list 1,2,3 &4 on the label]
- + Kills 99.9% germs<sup>1(,2)(,3)</sup>
- + Compatible (for)(with)(most) application equipment
- + Compatible (for)(with) sprayers
- + Reduce cross-contamination of germs between treated surfaces

- + Reduce the cross contamination of bacteria on treated, hard, nonporous surfaces
- + Eliminates food odors like garlic and onion left behind on kitchen surfaces after cooking
- + Eliminates odors caused by bacteria on food (contact) (preparation) hard, non-porous surfaces
- + Removes 99.9% of (kitchen\*\*\*) bacteria
- + Disinfects commonly touched hard, non-porous surfaces that can be transfer points for bacteria (such as doorknobs, telephones, keyboards and light switches)
- + Kills 99.9% of bacteria that can cause foodborne illness (food poisoning)<sup>2,3</sup>
- + Kills 99.9% of household pathogens\*\*\*\*

### **Non-living Allergen Claims**

- + Breaks down proteins of common allergens
- + Denatures allergens on hard, non-porous surfaces
- + Neutralizes allergens (on) (hard, nonporous surfaces) (and/or) ([insert any use site from list 1,2,3 & 4])

\*\*SARS-Related Coronavirus 2 (Isolate USA-WA1/2020), Poliovirus type 1 (ATCC VR-1562), Feline Calicivirus (Norovirus surrogate) (ATCC VR-782), Human Immunodeficiency virus type 1 (HIV-1) (HTLV-IIIB),Influenza A (H1N1) virus (ATCC VR-1469), H1N1 Influenza A virus CDC#2009712192, Herpes simplex virus type 2 (ATCC VR-734), Avian Influenza A (H7N9) virus (CDC#2013759189)

\*\*\*Salmonella enterica (ATCC 10708), Staphylococcus aureus (ATCC 15442), Listeria monocytogenes (ATCC 19117), Escherichia coli (ATCC 11229)

\*\*\*\* Salmonella enterica (ATCC 10708), Staphylococcus aureus (ATCC 15442), Escherichia coli (ATCC 11229), Trichophyton interdigitale mentagrophytes (ATCC 9533), Influenza A (H1N1) virus (ATCC VR-1469), Feline Calicivirus (Norovirus surrogate) (ATCC VR-782) [Note to reviewer: <sup>1, 2, and 3</sup> Reference both respective directions for use and appropriate target organism table.]

[Additional notes for reviewer]

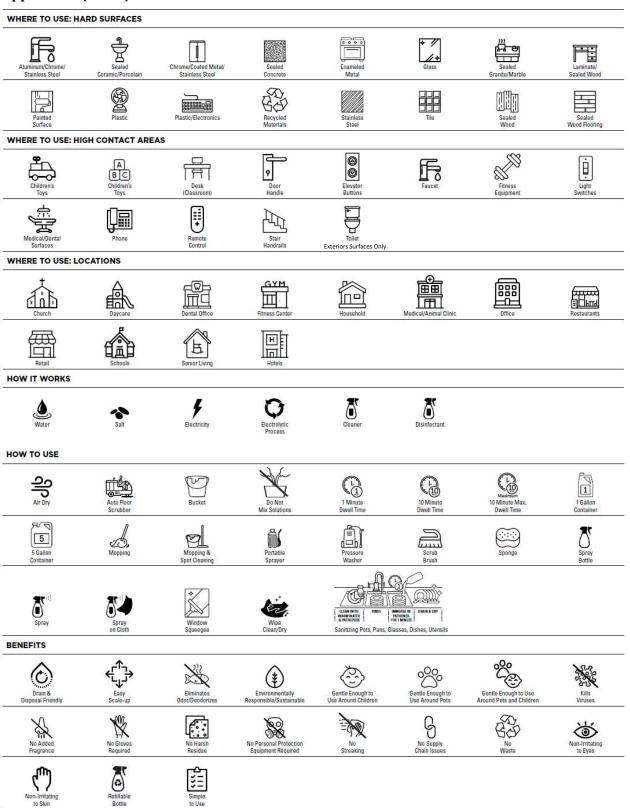
<sup>\*</sup>According to (directions for use)(-or-)(label instructions)

- + Now(!) -and/or- New(ly)(!) may be added anywhere to a claim and will only be used for the first 6 months of product on shelf.
- + Optional text may be placed anywhere on the label -and/or- container.
- + The word "and" may be substituted with "&". Plural words may be used in their singular form or singular words may be used in their plural form unless otherwise specified in 40 CFR.
- + When appropriate, multiple approved optional text statements may be linked together with the use of common conjunctions and prepositions so long as it does not create a statement that is false or misleading. Examples include but are not limited to: for, also, but, or, yet, additionally, so.
- + All directions may be written in numbered form or in paragraph form.
- + All use surfaces and/or use sites on the label may be listed in conjunction with an image of the use surface and/or use site.
- + Highlighted text is new. Strike-through and highlighted text means newly removed.
- + The product can be written as "Pathonex" or "PathoNex"

)

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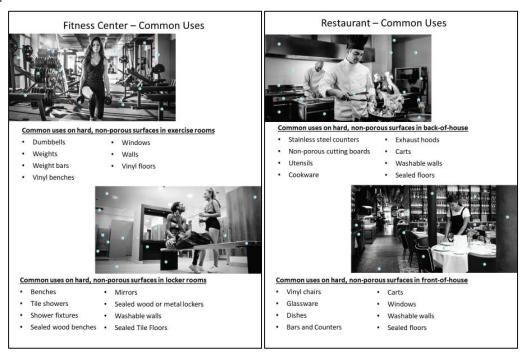
# Appendix A[Icons]:





### **Appendix B [Images-Use Sites]:**

[Note to reviewer: Images used below can have any approved use site or surface identified [via marker] from list 1,2,3,&4].

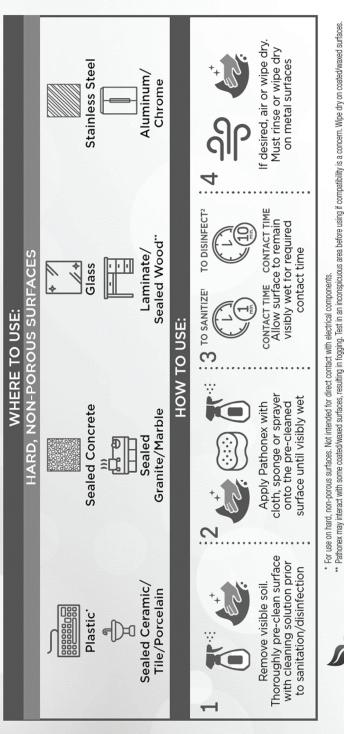




# Appendix C [Usage card to be used as a supplement to bottle label, not intended to be replacement to bottle label]:



Always pre-clean soiled surfaces with Pathopure™ or other cleaning solution before sanitizing/disinfecting with Pathonex. Reference bottle label for one-step kill claims.





PSUC231 @Spraying Systems Co. 2021

EPA Registration No.: 88161-1

Effective against Salmonella Enterica and Staphylococcus Aureus

SARS-Related Coronavirus 2, Poliovirus type 1, Feline Calicivirus (Norovirus surrogate), Human Immunodeficiency virus type 1 (HIV-1), Influenza A (H1N1) virus, 2009-H1N1 Influenza A virus (Novel H1N1), Herpes simplex virus type 2, Avian Influenza A (H7N9) virus, Trichophyton mentagrophytes, Salmonella entenica, Staphylococcus aureus, Pseudomonas aeruginosa, Listeria monocytogenes, Burkholderia cepacian, Methicillin Resistant Staphylococcus aureus – MRSA, Vancomycin Resistant Enterococcus faecalis – VRE, New Delhi metallo-beta-lactamase 1 (NDM-1) producing Klebsiella pneumoniae, Legionella pneumophila, Escherichia coli