



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 12, 2021

Juli Mann
Technology Sciences Group Inc.
1150 18th Street, NW, Suite 1000
Washington, D.C. 20036

Subject: PRIA Label Amendment – Add SARs-CoV-2 Claims
Product Name: Axen 30
EPA Registration Number: 72977-3
Application Date: December 21, 2020
Action Case Number/Decision Number: 00216808

Dear Ms. Mann:

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.

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

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with FIFRA section 6. If you have any questions, please contact Tiffany Green by phone at 703-347-0314, or via email at green.tiffany@epa.gov.

Sincerely,

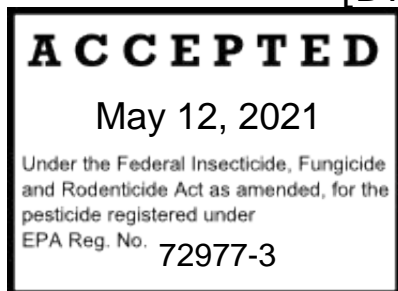


Aline Heffernan
Acting Product Manager Team 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure: Stamped Label

Axen® 30

[Disinfectant], [Fungicide] [& Virucide*]



[Disinfects and Deodorizes]

- [Restaurants] • [Hospitals] • [Schools] • [Homes] • [Offices] • [Trucks] • [Trailers] • [Shipping Containers] • [Rail Cars]

Manufactured by ETI H2O
A Division of PURE Bioscience
771 Jamacha Rd #512
El Cajon, CA 92019
EPA REG. No. 72977-3
EPA EST. No. [Enter establishment #]
Net Vol.
[Batch Number – may appear on container]

Active Ingredient

Silver Ion [†]	0.003%
Citric Acid	4.846%

Other Ingredients

	<u>95.151%</u>
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Total	100.000%
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[†] Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

NOTE: [Bracketed] text is optional wording ***Bold/italicized text is information only and not part of the label.***

DIRECTIONS FOR USE

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

AXEN® 30 [this product] is a colorless, odorless broad spectrum antimicrobial disinfectant and deodorizer. Proven to kill bacteria, fungus and viruses*, **AXEN® 30** [this product] is for use on hard non-porous non-food contact^s surfaces in ***Choose from the list below***

Homes [households]	patient transfer vehicles	prisons [jails]	airports
offices	hotels	kitchens ^s	school buses
hospitals	restaurants ^s	[public] restrooms	cars [autos]
nursing homes	bars ^s	bathrooms	RV [mobile home]
medical clinics	supermarket[grocery store]	washrooms	trucks
dental clinics	schools	laundry rooms	trailers
infirmary	colleges	bedrooms	shipping containers
blood bank(s)	dorm rooms [dormitories]	basements	rail cars
pharmacies	churches	garage(s)	subways
laboratories	shelters	workshops	trains
funeral homes	military [installations]	attics	airplanes
veterinary clinics	[locations]	locker rooms	ships
animal shelters	day care facilities	exercise facilities	cruise ships
kennels	daycare centers	gyms [gymnasium]	busses
cages	nurseries	beauty shops or salons)	other public
stables	playrooms	barber shops	transportation vehicles
catteries	playgrounds	spas	
animal transport vehicles	recreational facilities	health clubs	
ambulances		laundromats	

AXEN® 30 [this product] has been formulated to disinfect hard, non-porous non-food contact^s surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) and objects including ***Choose from the list below***

walls	stove tops	jungle gyms	desks
floors	bed frames	playhouses	grocery carts
counters	wheelchairs	baby furniture	computer keyboards
cabinets [cabinet handles]	over-bed tables	child car seats, hard	tanning beds
sinks	examination tables	surfaces only	sports equipment
tubs	waste containers	booster chairs [seats]	pharmacy equipment
exterior toilet [urinal] surfaces	tables	strollers [stroller handles]	FLAVORx® equipment
faucet handles	chairs	cribs	Pharmacy dispensing equipment
showers	patio furniture	playpens	cat litter boxes
doorknobs	equipment tables	activity centers	animal cages [carriers]
handrails	lab benches	diaper pails	
light switch covers	[AC] [heating] vents	diaper changing tables	
telephones	children's toys	potty[training] seats	
remote control (s)	toys	laundry hampers	
appliances	toy boxes	bathroom counters	
	play tables	kitchen counters ^s	

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

General Information

AXEN® 30 [this product] **successfully killed the following organisms under AOAC protocols (In order to ensure that all organisms listed are killed, you must use the contact times as directed in the Application Instructions):**

Organism	Kill Time
# <i>Pseudomonas aeruginosa</i>	30 seconds
# <i>Salmonella enterica</i>	30 seconds
<i>Staphylococcus aureus</i>	2 minutes
<i>Listeria monocytogenes</i>	2 minutes
Vancomycin resistant <i>Enterococcus faecium</i> (VRE)	2 minutes
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	2 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA)	2 minutes
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA-PVL)	2 minutes
<i>Escherichia coli</i> O157:H7	2 minutes
<i>Acinetobacter baumannii</i>	2 minutes
<i>Campylobacter jejuni</i>	2 minutes
Trichophyton mentagrophytes (Athlete’s Foot Fungus)	10 minutes
**HIV type 1- [Strain HTLV IIIB]	30 seconds
[#]*SARS-CoV-2 [(COVID-19 virus)]	30 seconds
*Herpes Simplex Type 1 [VR-733 F(1) Strain]	1 minute [60 seconds]
*Rotavirus	3 minutes
*Human Coronavirus	3 minutes
*Influenza A (H1N1)	1 minute [60 seconds]
*Swine Influenza A (H1N1)	1 minute [60 seconds]
*Respiratory Syncytial Virus [RSV]	3 minutes
*Adenovirus Type 2	3 minutes
*Murine Norovirus	10 minutes
*Norovirus [as Feline Calicivirus]	10 minutes
*Avian Influenza A	10 minutes
*Influenza A [VR-544, Hong Kong strain]	10 minutes
*Rhinovirus [R37 VR-1147, Strain 151-1]	10 minutes
*Polio Type 2, [VR-1002, Lansing Strain]	10 minutes

[Fungicidal Activity: AXEN® 30 [this product] is effective against *Trichophyton mentagrophytes*, the Athlete’s foot fungus, Use in locker rooms, dressing rooms, shower and bath areas, and exercise facilities.]

[Deodorizes: AXEN® 30 [this product] reduces annoying odors caused by bacteria. Use to control odors in hospitals, nursing homes, public restrooms, animal kennels and barn stalls. In private homes, use in the kitchen, bathroom, sink rooms and basements.]

APPLICATION INSTRUCTIONS

Pre-clean surfaces prior to using this product. For spray applications, apply from a distance of 6”-8”.

Disinfection:

For general disinfection and control of the bacteria on hard, non-porous surfaces *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Salmonella enterica*, *Listeria monocytogenes*, Vancomycin Resistant *Enterococcus faecium* (VRE), Methicillin Resistant *Staphylococcus aureus* (MRSA), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA), Community Associated Methicillin resistant *Staphylococcus aureus* (CA-MRSA-PVL), *Escherichia coli* O157:H7, *Acinetobacter baumannii* and *Campylobacter jejuni* the surface must be completely wet with **AXEN® 30** [this product] for 2 minutes. The surface may then be wiped dry with a clean towel.

NOTE: The following condensed instructions may be use in place of the above paragraph.

To kill bacteria on hard, non-porous, non-food contact surfaces, [apply] [spray] [mist] **AXEN® 30** [this product] until visibly wet for 2 minutes. The surface may then be wiped dry with a clean towel.

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

Fungus Control:

For effective control of the fungus *Trichophyton mentagrophytes* on hard, non-porous surfaces, the surface must be visibly wet with **AXEN® 30** [this product] for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

NOTE: The following condensed instructions may be use in place of the above paragraph.

To kill fungus on hard, non-porous surfaces, [apply] [spray] [mist] **AXEN® 30** [this product] to the surface until visibly wet for 10 minutes. The surface may then be wiped dry with a clean towel. Re-apply when cleaning or when new growth appears.

***Viral Control:**

To kill Herpes Simplex Type 1 [F(1) Strain], Rotavirus, Human Coronavirus, SARS CoV-2[(COVID19 virus)], Norovirus [as Feline Calicivirus], Murine Norovirus [MNV-1], Influenza A (H1N1), Swine Influenza A (H1N1), Avian Influenza A, Influenza A Virus [Hong Kong strain], Rhinovirus [R37 Strain 151-1], Respiratory Syncytial Virus [RSV], Adenovirus Type 2, and Polio Virus Type 2 [Lansing Strain] on hard, non-porous surfaces, the surface must be visibly wet with **AXEN® 30** [this product] for 10 minutes. The surface may then be wiped dry with a clean towel.

NOTE: The following condensed instructions may be use in place of the above paragraph.

To kill viruses on hard, non-porous surfaces, [apply] [spray] [mist] **AXEN® 30** [this product] to the surface until visibly wet for 10 minutes. The surface may then be wiped dry with a clean towel.

Kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings (or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of HIV): **Instructions for Cleaning and Decontamination Against HIV** on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids: **Personal Protection:** When handling items soiled with blood or body fluids, use appropriate barrier protection such as latex gloves, gowns, masks and eye coverings. **Cleaning Procedure:** Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfectant. **Contact Time:** Apply **AXEN® 30** [this product] to area to be treated. The surface must be visibly wet with **AXEN® 30** [this product] for 30 seconds. The surface may then be wiped dry with a clean towel. This contact time will not control all organisms listed on this label. Refer to application instructions for other organisms. **Disposal of Infectious Materials:** Blood and other body fluids should be autoclaved and disposed of according to federal, state and local regulations for infectious waste disposal.

KEY: The following language will be printed on the label of products intended to be sold to health facilities:

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

Optional refill instructions

To refill [spray bottles]:

1. [REMOVE] Remove trigger sprayer [or cap] from empty bottle
2. [POUR] Remove cap from refill and pour contents directly into empty [bottle].
3. [USE] Replace trigger sprayer and use as you normally would.

This statement will be used on NONREFILLABLE CONTAINERS.

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area away from direct sunlight at temperatures above freezing.

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

programs are run by state or local governments or by industry).
Container Handling: Nonrefillable Container. [Do not reuse or refill this container] –or- [Do not reuse or refill except as described in the directions for use. Refill only with this product.]. If empty: Place in trash or offer for recycling if available.

This statement will be used on REFILLABLE CONTAINERS (typically 55 gallons or larger).

STORAGE AND DISPOSAL

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

Pesticide Storage: Store in a cool, dry area away from direct sunlight at temperatures above freezing. Store in original container.

Pesticide Disposal: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a national Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Container Handling: Refillable Container. Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller.

IN CASE OF EMERGENCY

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact CHEMTREC 1-800-424-9300 (*or other emergency service provider*) for emergency medical treatment information.

NOTE: [Bracketed] text is optional wording ***Bold/italicized text is information only and not part of the label.***

Optional Marketing Phrases

[Kills] [Effective against] *Choose one or more from the list below:*

Salmonella enterica [in 30 seconds[†]]

Pseudomonas aeruginosa [in 30 seconds[†]]

Staphylococcus aureus

Listeria monocytogenes

Acinetobacter baumannii [in 2 minutes]

Campylobacter jejuni [in 2 minutes]

MRSA or [Methicillin Resistant Staph] or [Methicillin Resistant *Staphylococcus aureus*]

CA-MRSA or [Community Associated MRSA] or [Community Associated Methicillin Resistant *Staphylococcus aureus*]

CA-MRSA-PVL

VRE or [Vancomycin-resistant Enterococcus] or [Vancomycin resistant Enterococcus faecium]

Escherichia coli O157:H7

Tricophyton mentagrophytes

HIV [in 30 seconds[†]]

Herpes Simplex Virus

Influenza A Virus

Rhinovirus

Polio Virus Type 1

Rotavirus

Human Coronavirus

[SARS-related Coronavirus 2] [SARS CoV-2] [(COVID-19 virus)] [in 30 seconds[†]] on hard, non-porous surfaces

Norovirus virus [as Feline Calicivirus]

Avian Influenza A on pre-cleaned environmental hard surfaces

Respiratory Syncytial Virus [RSV]

Adenovirus [type 2]

Influenza A (H1N1) [in 1 minute]

Swine Influenza A (H1N1) [on pre-cleaned environmental hard surfaces] [in 1 minute]

Murine Norovirus [in the presence of 5% soil]

Kills bacteria and viruses in 30 seconds[†]

Kills [common] household germs

Kills germs [on surfaces you touch most]

Kills [common] household germs including [*Salmonella enterica*], [*Staphylococcus aureus*], [*Listeria monocytogenes*], and [*E. coli*].

Kills [*Salmonella*], [*Staphylococcus*], [*Listeria*], and [*E. coli*].

Kills – [Bacteria], [Fungus] and [Virus[†]]

Disinfects common household surfaces

Kills [common] cold] and [flu] virus[s]

[This product] [product name] is [Effective against] SARS-CoV-2 [the cause of COVID-19] on hard, non-porous surfaces

[Effective against] [Disinfects] [Kills] [Kills 99.99%] [Eliminates 99.99%] [of] SARS-CoV-2 [the cause of COVID-19] on hard, non-porous surfaces

[This Product] [Product Name] [Kills] [is] [Effective against] [Eliminates 99.99%] [of] [has demonstrated effectiveness against] SARS-CoV-2, the virus that causes COVID-19, on hard non-porous surfaces [in 30 seconds].

[This Product] [Product Name] [Kills] [is] [Effective against] [Eliminates 99.99%] [of] [has demonstrated effectiveness against] SARS-CoV-2 on hard non-porous surfaces [in 30 seconds].

[This Product] [Product Name] [Kills] [is] [Effective against] [Eliminates 99.99%] [of] [has demonstrated effectiveness against] SARS-related Coronavirus-2 on hard non-porous surfaces [in 30 seconds].

[This Product] [Product Name] [Kills] [is] [Effective against] [Eliminates 99.99%] [of] [has demonstrated effectiveness against] SARS-CoV-2 virus, [the virus that causes COVID-19] [responsible for COVID-19] on hard non-porous surfaces [in 30 seconds].

[This Product] [Product Name] Disinfects hard, non-porous surfaces by killing [99.99%] [of] SARS-CoV-2, [the virus that causes COVID-19] [responsible for COVID-19] [in 30 seconds].

[This Product] [Product Name] Disinfects hard, non-porous surfaces by killing [99.99%] [of] SARS-related Coronavirus-2, [the virus that causes COVID-19] [responsible for COVID-19] [in 30 seconds].

Can help reduce cross contamination between treated surfaces

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

Disinfectant, Fungicidal & Virucidal* Spray

[Patented] Silver Ion Formula

No dulling residue

Disinfects without bleaching

No chemical smell

Odor Free

Odorless

Disinfects hard, non-porous household surfaces

No Mixing Required

Powered by [Axenohl®] [SDC 2400] [Axenohl Alternate brand name]

For daily use

Refill

[Worldwide] Patented formula

[U.S.Patent(s) 6,197,814 ; 6,583,176, [additional patent numbers as issued]

Other patents pending

Use for a [fresh] [home] [environment]

Commercial [Line] [Disinfectant]

Industrial [Line] [Disinfectant]

Hospital [Line] [Disinfectant]

Healthcare [Line] [Disinfectant]

Consumer [Line] [Disinfectant]

Retail [Line] [Disinfectant]

Freight [Line] [Disinfectant]

Janitorial [Line] [Disinfectant]

Janitorial Disinfectant

Odoban® [Commercial], [Janitorial], [Earth Choice] (use restricted to the trademark owner)

[FAST[†]], [EASY], [EFFECTIVE]

[Antimicrobial] [antibacterial] disinfectant

Leaves surfaces disinfected

For use on high touch surfaces

Travel size

For use in *(insert use site from label)*

For use on *(insert use surface from label)*

[Ideal for] [Formulated for] [Hospitality Environment(s)] [Institutional] [Childcare Environment(s)] [Medical Environment(s)] [Nursing Environment(s)] [Healthcare Environment(s)] [Athletic Environment(s)] [Educational Environment(s)]

A New Generation of Protection

A New Generation Disinfectant

As seen on TV *may include graphic*



Made in the USA [may include graphic of American flag]

Use to disinfect FLAVORx® equipment

Recommended for use on FLAVORx® equipment

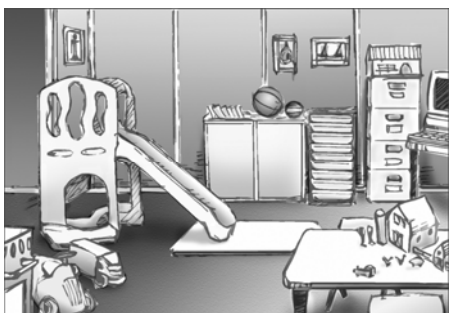
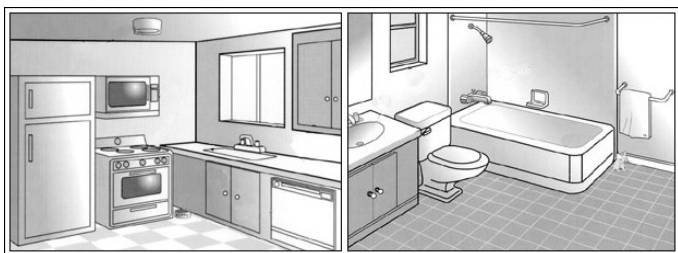
NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

KEY:

***-Refer to viruses**

‡-Refer to organisms controlled with 30 second kill time

Optional graphics for back of label (graphics are larger here than they will appear on the label)



NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*

THE FOLLOWING TABLE IS OPTIONAL TEXT:

Organism	ID
<i>Pseudomonas aeruginosa</i>	ATCC#15442
<i>Staphylococcus aureus</i>	ATCC#6538
<i>Salmonella enterica</i>	ATCC#10708
<i>Listeria monocytogenes</i>	ATCC#19111
Vancomycin resistant <i>Enterococcus faecium</i> (VRE)	ATCC#700221
Methicillin resistant <i>Staphylococcus aureus</i> (MRSA)	ATCC#700698
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA)	NRS123, USA 400
Community Associated Methicillin resistant <i>Staphylococcus aureus</i> (CA-MRSA-PVL)	NRS 192
<i>Escherichia coli</i> O157:H7	ATCC#43888
<i>Acinetobacter baumannii</i>	ATCC#19606
<i>Campylobacter jejuni</i>	ATCC#29428
Trichophyton mentagrophytes (Athlete's Foot Fungus)	ATCC#9533
*HIV type 1- Strain HTLV IIIB	HTLV-IIIB
*SARS-CoV-2 [(COVID-19 virus)]	USA-WA1/2020
*Herpes Simplex Type 1 VR-733 F(1) Strain	ATCC VR-733
*Rotavirus	Strain WA, Ottawa
*Human Coronavirus	ATCC VR-740
*Influenza A (H1N1)	ATCC VR-1469
*Swine Influenza A (H1N1)	ATCC VR-333
*Respiratory Syncytial Virus [RSV]	ATCC VR-26
*Adenovirus Type 2	ATCC VR-846
*Murine Norovirus	MNV-1.CW1
* Norovirus [as Feline Calicivirus]	ATCC VR-782
*Avian Influenza A	ATCC VR-2072
*Influenza A [VR-544, Hong Kong strain]	ATCC VR-544
*Rhinovirus [R37 VR-1147, Strain 151-1]	ATCC VR-1147
*Polio Type 2, [VR-1002, Lansing Strain]	ATCC VR-1002

NOTE: [Bracketed] text is optional wording **Bold/italicized text is information only and not part of the label.**

Emerging Viral Pathogen Claims

[Product name] [this product] qualifies for emerging viral pathogen claims per the EPA’s ‘Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels’ when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large, Nonenveloped viruses
- Small, Nonenveloped viruses

For an emerging viral pathogen that is a/an	...follow the directions for use for the following organisms on the label:
Enveloped virus	Adenovirus Type 2
Large, non-enveloped virus	Rhinovirus Type 37
Small, non-enveloped virus	Rhinovirus Type 37 Feline Calicivirus (surrogate for Norovirus)

[Product name] [this product] has demonstrated effectiveness against viruses similar to **[name of emerging virus]** on hard, nonporous surfaces. Therefore, [product name] [this product] can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on hard, nonporous surfaces. Refer to the [CDC -or- OIE] website at **[pathogen-specific website address]** for additional information.

-or-

[Insert name of illness/outbreak] is caused by **[insert name of emerging virus]**. [Product name] [this product] kills similar viruses and therefore can be used against **[name of emerging virus]** when used in accordance with the directions for use against **[name of supporting virus(es)]** on hard, nonporous surfaces. Refer to the [CDC -or- OIE] website at **[pathogen-specific website address]** for additional information.

{Note to Reviewer: These statements for claims against emerging viral pathogens shall not appear on marketed (final print) product labels.}

NOTE: [Bracketed] text is optional wording *Bold/italicized text is information only and not part of the label.*