



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

September 12, 2022

Brian King
Vice President of Manufacturing
MicroCare, LLC
595 John Downey Drive
New Britain, CT 06051-2435

Subject: Label Amendment: Adding the Emerging Viral Pathogens Claim
Product Name: OMC II Spray
EPA Registration Number: 46851-5
Receipt Date: 02/10/2022
Action Case Number: 00338979

Dear Mr. King:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Rotavirus is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, please contact Lorena Rivas at rivas.lorena@epa.gov.

Sincerely,



Heather A. Garvie
Senior Regulatory Advisor
Regulatory Management Branch 2
Antimicrobials Division
Office of Pesticide Programs

Enclosure: stamped label



ACCEPTED

09/12/2022

Under the Federal Insecticide, Fungicide
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 46851-5

[Kills [99.9% of] [viruses*] [and] [bacteria**] [in 1 minute†]]

OMC II Spray

[Alternative Brand Names:] [ProSpray™]

[Ready-to-Use] [Surface Disinfectant] [/] [Cleaner]

["One-Step†"] [Cleaner] [/] [Disinfectant] [/] [Deodorizer]

[The descriptive terms below are to be used, as applicable, depending on the microorganisms listed in the Effective Against Section.]

[Tuberculocidal] [,] [Virucidal*] [,] [Bactericidal] [,] [Fungicidal]

Kills Staphylococcus aureus - MRSA HA [ATCC 33592] in one minute

Kills Staphylococcus aureus - MRSA HA [ATCC 33592]

Active Ingredients

o-phenylphenol 0.28%

o-benzyl-p-chlorophenol 0.03%

Inert Ingredients 99.69%

Total 100.00%

E.P.A. Reg. No. 46851-5

E.P.A. Est. No. 46851-CO-003

[Lot #] [and] [expiration date] [printed on container]

Contents: [1 Gallon] [(3.79 liters)]

[Reorder No: _____]

Keep Out of Reach of Children

CAUTION: Irritant

Do Not Take Internally

[See other panels for additional precautionary statements.]

[PRODUCT BARCODE:] [+H816 _____]

FIRST AID:

IF SWALLOWED: Call a Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a Poison Control Center or doctor. Do not give anything by mouth to an unconscious person.

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IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a Poison Control Center or doctor for further treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for treatment advice.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

In case of an emergency for additional information call toll free 1-800-535-5053. Have the product container or label with you when calling a Poison Control Center or doctor, or going for treatment.

PRECAUTIONARY STATEMENTS:

Hazardous to humans and domestic animals.

CAUTION: Harmful if swallowed, absorbed through skin or inhaled. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid breathing spray mist. Remove and wash contaminated clothing before reuse.

USER SAFETY REQUIREMENTS: Follow manufacturers' instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. [Users must wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.]

[Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels are required. The last equipment/instrument/hard, non-porous surface listed will be preceded with the word "and".]

ProSpray™ is an effective "one-step†" cleaner and broad-spectrum disinfectant [according to the AOAC Use-Dilution Test], [modified in the presence of 5% organic soil load] when disinfection directions are followed for all listed organisms.

This product [cleans] [,] disinfects [and] [deodorizes] hard nonporous surfaces in one labor-saving step when disinfection directions are followed for all listed organisms.

[ProSpray™ may be used in [healthcare,] [office,] [transport,] [commercial] [and] [home] [settings] [on] [vinyl,] [plastics,] [metals,] [floors,] [walls,] [counters,] [carts] [and] [bedside equipment].]

ProSpray™ is effective against the following microorganisms on hard non-porous surfaces when used as directed:

EFFECTIVE AGAINST:

MYCOBACTERIUM TUBERCULOSIS VAR. BOVIS [(TB)]

ADENOVIRUS TYPE 5 ATCC VR-5* (when used as directed in application as a spray.)

STAPHYLOCOCCUS AUREUS ATCC 6538**

STAPHYLOCOCCUS AUREUS - MRSA HA ATCC 33592**

SALMONELLA ENTERICA ATCC 10708**

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PSEUDOMONAS AERUGINOSA ATCC 15442**
HIV-1 [(AIDS VIRUS)]*
HERPES SIMPLEX VIRUS TYPE 1 ATCC VR-733 & TYPE 2 ATCC VR-734*
TRICHOPHYTON INTERDIGITALE ATCC 9533

DIRECTIONS FOR USE:

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

[The following paragraph will be included in its entirety when the production label references healthcare use.]

ProSpray™ is designed for use on hard non-porous surfaces and/or in holding solution. 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 or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

CLEANING: [ProSpray™ is an effective ready-to-use cleaning agent.] Apply ProSpray™ directly to surface using [spray] [bottle] [or] [mop]. Wipe surface to remove debris and solution using [clean] [paper] [or] [cloth] [towels] and discard. [Occasional [rinsing] [or] [wiping] [with] [damp] [cloth] is recommended when ProSpray™ is used frequently [on [floors,] [stainless steel,] [vinyl] [and] [other surfaces].]

[MEDICAL AND DENTAL INSTRUMENT HOLDING SOLUTION and ULTRASONIC INSTRUMENT CLEANING DEVICES: Fill [container] [or] [tank] [of ultrasonic cleaning device with fresh [ready-to-use] ProSpray™]. [[Soak] [or] [operate device] [for 5 minutes.] Rinse articles thoroughly with potable water and pat dry. Package and sterilize instruments prior to use. The efficacy of the solution is compromised in the presence of organic matter. Use a fresh solution [daily] [or] [change] [more often] [if it becomes [diluted] [or] [soiled]. [For use on [metals] [,] [plastics] [,] [rubber] [and] [glass].]

[FOR CLEANING HAIR CLIPPERS AND ELECTRIC SHEARS: While [clipper] [/] [electric shear] is running, hold [clipper] [/] [electric shear] in downward position and spray ProSpray™ to thoroughly wet the blades. [Avoid spraying on the [clipper] [/] [electric shear] case or dripping into the [clipper] [/] [electric shear] housing.] Rinse [clipper] [/] [electric shears] and follow with [appropriate] [lubricating] [and] [disinfection] [process].]

[FOR CLEANING SALON IMPLEMENTS AND SHEARS: Spray ProSpray™ to thoroughly wet the [implement] [or] [shear]. [Wipe away visible debris using [a] [soft] [bristle] [brush] [or] [cloth]]. Rinse [implement] [or] [shear] and follow with [appropriate] [lubricating] [and] [disinfection] [process].]

DISINFECTION: For visibly soiled areas, a pre-cleaning step is required. [ProSpray™ may be used for this purpose.] Use fresh solution daily or change more often if it becomes diluted or soiled when used [in [buckets,] [soak pans] [and] [ultrasonic] [instrument cleaning devices]. Apply ready-to-use ProSpray™ to hard non-porous surfaces [such as floors,] [walls,] [counters] [and] [tables] [with [mop] [or] [spray] [using [clean] [paper] [or] [cloth] [towel]]]]. All surfaces must remain visibly wet for one minute. Use a five minute contact time to inactivate TB. To disinfect against Adenovirus TYPE 5, product must be applied as a spray and allow surface to remain visibly wet for five minutes. Allow to air dry or remove excess with [clean] [mop] [,] [cloth] [or] [sponge]. [[Wipe] [or] [rinse] surfaces periodically after disinfection.]

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CONTACT TIMES:**ONE MINUTE EXPOSURE[‡]:**

Staphylococcus aureus**, Staphylococcus aureus - MRSA HA**, Salmonella enterica**, Pseudomonas aeruginosa**, HIV-1 [(AIDS virus)]*, Herpes simplex virus types 1 & 2*, Trichophyton interdigitale

FIVE MINUTE EXPOSURE:

Mycobacterium tuberculosis var. bovis [(TB)], Adenovirus TYPE 5 (when used as directed in application as a spray.)

FOR USE AS A DISINFECTANT ON PRECLEANED NON-CRITICAL MEDICAL DEVICES, INSTRUMENTS AND IMPLEMENTS: Instruments must be thoroughly cleaned to remove excess organic debris [ProSpray™ may be used for this step], rinsed and dried. Apply ProSpray™ to pre-cleaned surfaces, thoroughly wetting areas to be disinfected. Allow surfaces to remain visibly wet for 5 minutes at room temperature [(68°F / 20°C)]. Rinse instruments and wipe dry prior to use.

[The following HIV instructions are to be included on production labels when claims against HIV are listed.]

ProSpray™ kills HIV-1 on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in healthcare settings or other settings in which there is an expected likelihood of soiling 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 human immunodeficiency virus Type-1 HIV-1 [(associated with AIDS)].

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV ON SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS:

PERSONAL PROTECTION: When handling items soiled with blood or body fluids or when conducting procedures which might lead to contact with blood or body fluids, always wear items such as disposable gloves, gowns, masks and eye coverings.

CLEANING PROCEDURES: Blood and body fluids must be thoroughly cleaned from surfaces and objects before application of ProSpray™. [ProSpray™ may be used for this purpose.]

CONTACT TIME: Allow surface to remain visibly wet for one minute to kill [HIV-1 [(AIDS Virus)]].

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

STORAGE AND DISPOSAL:

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

PESTICIDE STORAGE: Store in original container in an area inaccessible to persons unfamiliar with its use.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental

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Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill or by procedures approved by state and local authorities.

[Optional Marketing Claims:]

[Lemon Scent.]

[Fresh Scent.]

AREAS OF USE:

NURSING, HOSPITAL AND HEALTHCARE SETTINGS:

Ambulatory Surgical Centers[(ASC)]

Anesthesia Department

Cat Labs

CCU

Central Supply Clinics

Clinics

Dental Offices

Dialysis

Doctors' Offices

Donation Centers [(Apheresis, Blood, Milk, Plasma, Semen)]

Emergency Medical Settings

Emergency Rooms

Endoscopy Centers

Eye Surgical Centers

GI Centers

Hospices

ICU

Isolation Areas

Laboratory

Laundry Rooms

Operating Rooms[(OR)]

Ophthalmic Offices

Orthopedics Department

Out-patient Surgical Centers[(OPSC)]

Patient Care Areas

Physical Therapy Offices

Radiology Department

Reception Areas

Recovery Rooms

Rehabilitation Department

Respiratory Therapy Offices

Surgery Department

Waiting Room

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OFFICE AND HOME SETTINGS:

Libraries
Manufacturing Facilities
Office Buildings
Public Facilities
Schools
Cabinets
Computers
Counters
Desks
Doorknobs
Fax Machines
Filing Cabinets
Garbage Cans
Hard Surfaces on Headsets
Keyboards
Public Telephones
Railings
Seats
Sinks
Tables
Tabletops
Telephones
Work Stations

EMERGENCY SERVICES SETTINGS:

Ambulances
Police Cars
Transport Vehicles

VETERINARY SETTINGS:

Isolation Areas
Veterinary Clinic
Waiting Room

HEALTH CLUB FACILITIES AND GYMS:

Gym Equipment
Locker Rooms
Reception Areas
Showers

SALONS, ESTHETICIANS, BARBER SHOPS:

Beauty Shops
Manicure Salons
Spas
Tattoo Parlors

BATHROOMS:

Basins
Bathroom Fixtures
Bathtubs
Cabinets
Countertops
Doorknobs
Faucets
Glazed Tiled Walls
Hampers
Handles

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BATHROOMS (continued):

Handrails

Showers

Sinks

Toilet Exteriors [(Exterior Surfaces of Toilets)]

Urinals [(Exterior Surfaces of Urinals)]

Vanity Tops

TRANSPORT SERVICE SETTINGS:

Fire Trucks

School Buses

Transport Vehicles

Hard Plastic or Metal Flooring

Seats

Steering Wheel

Walls

HARD NON-POROUS SURFACES:

Adapter Rings

Bed Frame

Bidet

Hard Surfaces on Booster Seats

Brass

Brushes

Chrome

Clean-up Carts

Clipper Blades

Combs

Copper

Crystal

Cuspidors

Dental Chairs

Dental Units

Digital X-Ray Sensors

Drains

Dressing Carts

Drinking Fountains

Electric Shears

Enamel

Examination Tables

Fixtures

Floors

Furniture [(Non Wood)]

Glass

Glazed Ceramic Tile

Glazed Porcelain Tile

Grocery Cart Handles

Grocery Cart Child Seats

Hair Care Implements

Hair Clippers

Hard Non-Porous Outdoor Furniture

Laminate

Lamps

Light Switches

Linen Carts

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HARD NON-POROUS SURFACES (continued):

Linoleum
Litter Boxes
Manicure Implements
Manicure Tables
Marble [(Culture, Synthetic)]
Marlite
Metal
Metal Blinds
Mirrors
Nail Implements
Non-Porous Dental Impression Material
Parquet
Patient Chairs
Pens
Plastic
Plastic Mattress Covers
Portable Toilet
Recycling Bins
Remote Controls
Resilient [(Ceramic)] Floor
Salon Surfaces
Sealed Granite
Sealed Wood
Shears
Sports Equipment
Stainless Steel
Stretchers
Tin
Tools
Vinyl
Wheelchairs
Whirlpool Interiors
Windows

HARD NON-POROUS USE SITES:

Attic
Automobile
Basement
Bathroom
Bedroom
Boat
Cabin
Camper
Closet
Den
Dining Room
Dorm
Family Room
Living Room
Garage
Home
Kitchen
Laundry Room

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HARD NON-POROUS USE SITES (continued):

Locker
Mobile Home
Mudroom
Pet Area
Public Places
Storage Area
Studio
Sunroom
Tool Shed
Workshop

HARD NON-POROUS PROFESSIONAL USE SITES:

Barber Shops
Beauty Shops
Blood Bank
Clinic
College
Commercial Building
Correctional Facilities
Dental Office
Doctors' Office
Grocery Store
Gymnasium
Health Care Facility
Health Club
Hospital
Hotel
Motel
Kennel
Laboratory
Laundromat
Libraries
Manicure Salons
Manufacturing Facilities
Military Installation
Morgues
Mortuaries
Nursing Home
Office Building
Patient Room
Pharmacy
Public Places
Recreational Center
Restroom
Salon
Schools
Shelter
Sick Room
Spas
Tattoo Parlors
Veterinary
Warehouse Club

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[ProSpray is recommended for use in healthcare settings.]

[ProSpray is intended for use [on] [/] [in] non-critical medical [devices] [/] [settings].]

[ProSpray is a multi-purpose [disinfectant][/][decontaminant] [cleaner] for use on hard non-porous inanimate surfaces.]

[ProSpray will effectively clean and disinfect, when disinfection directions are followed for all listed organisms.]

[Non-critical medical devices are items that come in contact only with intact skin.]

[ProSpray is an effective method to clean against odor-causing organisms on hard non-porous surfaces listed on this label.]

[Indicated for use when manufacturer's instructions recommend avoiding alcohol [on] [vinyls] [or] [plastics].]

[Water-based intermediate-level disinfectant]

[Broad based material compatibility]

[The following statement is to be included on production labels when food contact areas or surfaces are listed:]

A thorough rinse with potable water is required for surfaces in direct contact with food.

[†]When disinfection directions are followed for all listed organisms.



595 John Downey Drive
New Britain, CT 06051 USA
Main: (860) 827-0626
www.MicroCare.com

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{Emerging Viral Pathogen Claims}

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 category[ies]:

- Enveloped viruses

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

Acceptable claim language:

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

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

[PSC/EPA/TX09 08/22]

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