



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

WASHINGTON, D.C. 20460

April 30, 2024

Brian Keith
MicroCare, LLC
6120 E 58th Avenue
Commerce City, CO 80022
Electronic Transmittal: [SarahWalker@microcare.com]

Subject: Notification per PRN 98-10 – Adding Additional Alternate Brand Name
Product Name: Omni II™
EPA Registration Number: 46851-1
Received Date: 09/06/2023
Action Case Number: 484119

Dear Mr. Keith:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Antimicrobials Division (AD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped “Notification” and will be placed in our records.

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) 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. 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.

Also, the following alternate brand name has been added to the product record:

- SpecClean™ Concentrated Disinfectant

If you have any questions, you may contact Stacey Grigsby at 202.566.0821 or via email at grigsby.stacey@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Stacey Grigsby".

Stacey Grigsby
Regulatory Risk Manager, 34
Regulatory Management Branch II
Antimicrobials Division (7510M)

NOTIFICATION

48651-1

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

04/30/2024



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

Omni II™

[Alternative Brand Names:] [ProSpray C-60™] [Vital Defense®-D] [ProPhene™ plus] [Spec Clean™ Concentrated Disinfectant]



[Concentrated] [Surface Disinfectant] [,] [Cleaning] [and] [Holding Solution]

[“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	9.0%
o-benzyl-p-chlorophenol	1.0%
Inert Ingredients	90.0%
Total	100.0%

E.P.A. Reg. No. 46851-1

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

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

Contents: [1 Quart] [(32 oz.) [-] [946 ml.]]

[Reorder No: _____]

Keep Out of Reach of Children

DANGER

Do Not Take Internally

[See other panels for additional precautionary statements.]

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[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.

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.

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

PRECAUTIONARY STATEMENTS:

Hazardous to humans and domestic animals.

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Harmful if inhaled, swallowed or absorbed through skin. Do not get in eyes, on skin or on clothing. Wear goggles, face shield, or safety glasses, and protective clothing (long-sleeved shirt and long pants, socks, plus shoes and chemical resistant gloves such as water proof gloves). Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

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.] Users must remove clothing immediately if pesticide gets inside. Wash thoroughly and put on clean clothing.

[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".]

Omni II™ 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.

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

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

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

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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**
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.]

Omni II™ 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: [Omni II™ is an effective cleaning agent.] [Prepare [a fresh 1:32 use solution of] Omni II™ and apply 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 Omni II™ is used frequently [on [floors,] [stainless steel,] [vinyl] [and] [other surfaces].]

[MEDICAL AND DENTAL INSTRUMENT HOLDING SOLUTION and ULTRASONIC

INSTRUMENT CLEANING DEVICES: Prepare [a 1:32 use solution of] Omni II™ in [holding container] [or] [ultrasonic cleaning device]. [[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. Prepare a fresh solution [daily] [or] [change] [more often] [if it becomes [diluted] [or] [soiled]. [Effective in waters up to 400 ppm hardness calculated as calcium carbonate.] [For use on [metals] [,] [plastics] [,] [rubber] [and] [glass].] [Glass may etch over prolonged or repeated exposure to concentrated solutions.] [Do not store lensed articles in concentrated Omni II™.]

[FOR CLEANING HAIR CLIPPERS AND ELECTRIC SHEARS: While [clipper] [/] [electric shear] is running, hold [clipper] [/] [electric shear] in downward position and spray [a prepared 1:32 use solution of] Omni II™ 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 [with prepared 1:32 use solution of] Omni II™ 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].]

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DISINFECTION: For visibly soiled areas, a pre-cleaning step is required. [Omni II™ may be used for this purpose.] Prepare a 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 1:32 use solution of Omni II™ 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]. A properly prepared solution of Omni II™ has a use life of 30 days after dilution when stored in a closed container such as a spray bottle. [[Wipe] [or] [rinse] surfaces periodically after disinfection.]

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 [Omni II™ may be used for this step], rinsed and dried. Apply Omni II™ 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.

TO PREPARE 1:32 USE DILUTION

To Make:

1 Pint

Water 15 ½ fluid oz.

Omni II™ ½ fluid oz. (15 ml)

1 Quart

Water 31 fluid oz.

Omni II™ 1 fluid oz. (30 ml)

½ Gallon

Water 62 fluid oz.

Omni II™ 2 fluid oz. (60 ml)

1 Gallon

Water 124 fluid oz.

Omni II™ 4 fluid oz. (120 ml)

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

Omni II™ 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 Omni II™. [Omni II™ 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 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. **Triple rinse (or equivalent) promptly after emptying.** Discard rinsate in accordance with Pesticide Disposal instructions. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by procedures approved by state and local authorities.

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[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

OFFICE AND HOME SETTINGS:

Libraries
Manufacturing Facilities
Office Buildings
Public Facilities
Schools
Cabinets
Computers
Counters
Desks
Doorknobs
Fax Machines

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OFFICE AND HOME SETTINGS (continued):

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
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

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TRANSPORT SERVICE SETTINGS (continued):

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

Linoleum

Litter Boxes

Manicure Implements

Manicure Tables

Marble [(Culture, Synthetic)]

Marlite

Metal

Metal Blinds

Mirrors

Nail Implements

Non-Porous Dental Impression Material

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HARD NON-POROUS SURFACES (continued):

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

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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

[Omni II™ is recommended for use in healthcare settings.]

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

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

[Omni II™ 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.]

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[Omni II™ 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
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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.

[OMN2/EPA/TX11 09/23]

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