

88494-1

09/27/2012

1/12



U S ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D C 20460

EPA Reg
Number

88494-1

Date of Issuance

SEP 27 2012

Term of Issuance

Unconditional

Name of Pesticide Product

Wedge Disinfectant

NOTICE OF PESTICIDE

- Registration
- Reregistration

(under FIFRA as amended)

Name and Address of Registrant (include ZIP Code)

North American Infection Control Ltd
209 Strathearn Road
Toronto, Ontario M6C1S5 Canada

Note Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant the above named pesticide is hereby registered/reregistered under the Federal Insecticide Fungicide and Rodenticide Act

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency In order to protect health and the environment the Administrator on his motion may at any time suspend or cancel the registration of a pesticide in accordance with the Act The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others

This product (OPP Decision No D-464964) is conditionally registered in accordance with FIFRA sec 3(c)(7)(A) provided that you

1 Submit and/or cite all data required for registration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data and submit acceptable responses required for re registration of your product under FIFRA section 4

2 Make the labeling changes listed below before you release the product for shipment

- a Revise the EPA Registration Symbol to read EPA Reg No 88494 1'
- b Add an asterisk to terms Virus and Virucidal such that it refers to the list of viruses mitigated by this product

Signature of Approving Official

Jacqueline Campbell
Jacqueline Campbell
Product Manager Team-34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Date

SEP 27 2012

- c Delete the 16th claim on page 3 because efficacy data to support this claim was not submitted
- d Delete all 'sanitize' claims on the label since efficacy data was not submitted to support them
- e Delete the last statement in the 5th claim on page 5
- f Since this product is used in Animal Housing/Holding Facilities you must add the following directions to the label in accordance with DIS/TSS-18

Veterinary Clinics, Animal Life Science Laboratories, Pet Shops

Remove all animals and feed from premises vehicles and enclosures Remove all litter and manure from floors walls and surfaces of facilities and fixtures occupied or traversed by animals Empty all troughs, racks and other feeding and watering appliances Thoroughly clean all surfaces with soap or detergent and rinse with water Wet surfaces for 1 minute Immerse all handling and restraining equipment as well as forks, shovels and scrapers used for removing litter and manure Ventilate buildings, vehicles and other closed spaces Do not house animals or employ equipment until treatment has been absorbed set or dried Thoroughly scrub treated feed troughs, racks and other feeding and watering appliances with soap or detergent then rinse with potable water before reuse

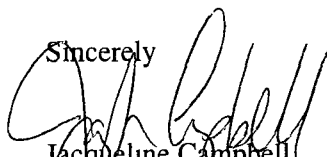
- g Revise the last bullet on page 9 by deleting the brackets around 'packaging' Agency has limited renewable resource claims to packaging it is not optional

3 Submit a 1 year storage stability and corrosion characteristic study following OPPTS 830 6317 and 830 6320 guidelines one year from the date of this notice

4 Submit three (3) copies of your final printed labeling before distributing or selling the product bearing the revised labeling

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec 6(e) Your release for shipment of the product constitutes acceptance of these conditions

A stamped copy of the label is enclosed for your records Should you have any questions regarding this letter please contact Lorena Rivas by telephone at (703) 305-5027 or by email at rivas.lorena@epa.gov

Sincerely

Jacqueline Campbell
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

Wedge Disinfectant

Note to Reviewer – Text in [] is Optional Text Which May or May Not be Capitalized
Note to Reviewer – The Following is a List of Additional Brand Names for This Product

- Disinfectant Solution #1
- Disinfecting Solution #1
- Medical Disinfectant #1
- Medical Surface Disinfectant
- Medical Surface Disinfectant #1
- Surface Disinfectant #1
- Surface Disinfecting Solution #1
- Dental Disinfectant #1
- Dental Disinfecting Solution #1
- Dental Disinfectant and Presoak
- Veterinary Disinfecting Solution
- Veterinary Disinfectant #1

ACCEPTED
with COMMENTS
in EPA Letter Dated

SEP 27 2012

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

88494-1

ACTIVE INGREDIENTS	
Ethyl Alcohol	72 50%
Didecyl Dimethyl Ammonium Chloride	33%
OTHER INGREDIENTS	27 17%
Total	100 00%

Keep Out of Reach of Children

CAUTION

See [back] [side] panel for additional precautionary statements

EPA Reg No 88494-X
EPA Est No XXXXX-XX-X

[Made] [Manufactured] for
North American Infection Control Ltd
209 Strathearn Road
Toronto, Ontario M6C1S5 Canada

[Distributed] [in the] [United States] [US] [by]
XXXXXXXXXXXXXXXXXXXX
XXXXXXXXXXXXXXXXXXXX

NET CONTENTS X lbs X ozs
[1 gallon] [1 quart] [1L] [1 pint] [500 ml] [8 oz] [220 ml]

Note to Reviewer – The Statements on This Page and the Following Page are Optional Statements

[EFFECTIVE] [WORKS] [KILLS PATHOGENS/ BACTERIA/FUNGI/VIRUSES] [IN ONE MINUTE/60 SECONDS]
 [ONE MINUTE] [CLEAN AND DISINFECT] [ONE STEP] [ONE PRODUCT] [ONE SOLUTION]
 [NEW][QUICK][EASY][EFFECTIVE][FAST AND EFFECTIVE] [CONVENIENT]
 [CLEANS, DISINFECTS & DEODORIZES]
 [ALL PURPOSE] [CLEANER] [DEODORIZER] [DETERGENT] [DISINFECTANT]
 [INSTRUMENT PRESOAK] [PRESOAK]
 [ANTIBACTERIAL] [DETERGENT] FORMULA CLEANS [and] DISINFECTS and DEODORIZES]
 [UNSCENTED] [FRAGRANCE FREE]
 [BLEACH-FREE]
 [BACTERICIDAL] [TUBERCULOCIDAL] [FUNGICIDAL] [VIRUCIDAL]
 [Kills Viruses Most [Responsible for] [Associated with] the Common Cold]
 [Kills Antibiotic Resistant Bacteria such as MRSA and VRE]
 Kills Flu Virus
 Kills Pandemic 2009 H1N1 Influenza A virus [formerly called swine flu]

- [Antibacterial] [Disinfecting] and scrubbing power all in one
- 99 99% effective in killing common [household] [kitchen] [bathroom] bacteria
- Antibacterial [detergent] formula cleans and [disinfects] [sanitizes] in one step
- [Antimicrobial] [Antibacterial] [spray] [instrument presoak]
- [Clean] and [Sanitize] and [Disinfect] non-porous surfaces [in any room in the house] [throughout the house]
- [Clean] and [Sanitize] and [Disinfect] any room in the house
- [Clean] and [Sanitize] and [Disinfect] patient and public areas in [hospitals] [medical offices] [dental offices] [ambulatory care facilities] [veterinary offices] [nursing homes] [long term care facilities] [ambulances] [residential sick rooms] [mortuaries]
- Cleaning made easy for all your hard, non-porous surfaces
- Cleans and cuts grease
- Cleans tough stains
- Cleans, [sanitizes] [disinfects] and deodorizes
- Cuts through tough grime
- Easy Cleaning [Around the house]
- Easy to use
- Effective against odor-causing bacteria
- Effective daily use
- Effective in [sanitizing] [disinfecting] your [kitchen] [bathroom] [Medical] [Dental] [Veterinary] [Institutional] surfaces
- Eliminates odors
- Fast and easy way to clean
- Fast and effective cleaning
- For all non-porous household surfaces

- For all your [heavy] [light] duty jobs
- Ideal for cleaning and [sanitizing] [disinfecting] any non-porous surface
- Kills common [household] [kitchen] [bathroom] bacteria
- Fragrance Free
- Leaves your [bathroom] [kitchen] fresh and clean
- One-step cleaning
- One-step clean and disinfect
- Quick cleaning
- [Sanitize] [Disinfect] your household surfaces highchairs, booster seats, strollers, car seats, cribs, tabletops, countertops, appliance exteriors, sinks, and glazed tiles
- Saves time
- Use every day in every room [throughout the house] [throughout the institution] [throughout the office]
- Use in [public toilets] [Laundromats] [pet areas] [hotels] [motels] [lodging establishments] [manufacturing facilities] [factories] [offices] [office buildings] wherever [sanitizing] [disinfecting] is important
- Use on hard, non-porous surfaces [stainless steel] [Formica®] [glass] [glass tables] [glazed porcelain] [plastic]
- [This product or product name] cleans and/or disinfects and/or deodorizes
- [Antibacterial] [Disinfectant] [Detergent] [formula] [Cleans and] Disinfects in [just] 1 minute
- Kills 99.99% of bacteria that can cause food borne illness on hard, non-porous surfaces in [just] [1 minute] [60 seconds]
- Leaves hard, non-porous surfaces disinfected
- One step [cleaning] and /or [disinfecting] and/or [deodorizing]

Note to Reviewer – Not All of the Following Locations Will Be Listed On All Product Versions

[This product or product name] is intended for use in

- Hospitals and healthcare settings, including Ambulances, Anesthesia, CAT Labs, CCU, Central Supply, Clinics, Dental Offices, Dialysis Clinics, Doctor's Office[s], Emergency Rooms, [E R], Food Service and Food Prep Areas, Home Health Care Hospices, Laboratory, Laundry Rooms, Long Term Care Facilities Newborn Nursery, Nursing Homes, Offices, Operating rooms, Pediatrics, Physical Therapy, Physician's Office[s], Ophthalmic Offices, Radiology, Recovery Room, Rehabilitation, Respiratory Therapy, Ultrasound, Transport Vehicles, Waiting Areas, X-Ray
- Critical Care Areas [CCU] Cardiac Care Units, [E R] Emergency Rooms, [ICU] Intensive Care Units, [NICU] Neonatal Intensive Care Units [PICU] Pediatric Intensive care Units, Surgery, Surgical Prep and Surgical Recovery Units
- Animal Holding Areas, Animal Hospitals, Animal Life Science Laboratories, Animal Transportation Vehicles, Breeding Establishments, Grooming Establishments, Kennels, Pet Shops, Tack Shops, Veterinary Clinics, Veterinary Examination Rooms, Veterinary Operating Rooms, Veterinary Waiting Rooms, Veterinary X-Ray Rooms, Zoos
- Barber Shops Beauty Salons, Correctional Facilities, Funeral Homes, Mortuaries
- Airports, Athletic Facilities, [Gyms] Gymnasiums Health Clubs, Schools Transportation Terminals
- Banquet Halls, Catering Facilities, Delicatessens, Grocery stores Shopping Centers, Restaurants
- Childcare Facilities Daycare Centers, Nurseries
- Households, Homes, Residences, Kitchens and/or Bathrooms
- Institutional Kitchens and/or Bathrooms [Restrooms] [Toilet Facilities]
- Food Processing and Food Packaging Facilities

Note To Reviewer - The Following Specific Product Uses May or May Not Be Listed On All Product Versions

[This product or product name] will clean and disinfect hard non-porous surfaces of bed railings, cabinets, carts, chairs, counters, exam tables, gurneys, isolettes, IV poles, stethoscopes, stretchers, tables, telephones, toilet seats, toilets, bathtubs, bathroom fixtures, shower stalls, sinks, tiles, vanity tops, hospital beds, traction devices, MRI, CAT, scales, paddles, wheelchairs, ultrasound transducers and probes

[This product or product name] will clean and disinfect hard, non-porous surfaces of grocery cart handles, grocery carts, shopping carts grocery cart child seats

[This product or product name] will clean and disinfect hard, non-porous surfaces of changing tables cribs, diaper pails trashcans, garbage cans

[This product or product name] will clean and disinfect hard, non-porous surfaces of cabinets, chairs, computers, countertops, desks, desktops, doorknobs, fax machines garbage cans, headsets, keyboards, railings, seats, sinks, tables, tabletops, telephones, trashcans appliance exteriors, [bathroom][kitchen] faucets, bathtubs, shower [doors][stalls], stove tops

[This product or product name] will clean and disinfect hard, non-porous surfaces of gym equipment, exercise machines, non-porous wrestling/gymnastic/exercise/yoga mats, gymnastic [athletic] equipment

Use [this product or product name] to clean and disinfect non-porous personal protective safety equipment, protective headgear, hard hats, half mask respirators, full face breathing apparatus, gas masks, goggles, spectacles, face shields, silicone rubber or PVC hearing protectors and vinyl covered ear muffs Rinse all equipment that comes in prolonged contact with skin before reuse with clean warm water [about 120°F], and allow to air dry [Caution Cleaning at the 120°F temperature will avoid overheating and distortion of the personal safety equipment that would necessitate replacement]

[This product or product name] is formulated to disinfect hard, non-porous, inanimate environmental surfaces such as floors, walls, metal surfaces, stainless steel surfaces, glazed porcelain, glazed ceramic tile, plastic surfaces, bathrooms, shower stalls, bathtubs, and cabinets

[This product or product name] helps prevent cross contamination from contact with treated surfaces Helps protect patients, staff, family members and visitors

DIRECTIONS FOR USE

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

For labels that list medical premises one of the following statements must be used

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body

or

This product is not for use on critical and semi-critical medical device surfaces

CLEANING Wet surface sufficiently and clean with a mop sponge, cloth, nonwoven wipe or other suitable cleaning instrument

DISINFECTING To disinfect hard, non-porous surfaces, thoroughly wet the surface to be treated. Treated surface must remain visibly wet for one [1] minute to achieve complete disinfection [or kill] of all pathogens listed on this label. For visibly soiled surfaces clean before following disinfecting instructions. Allow surfaces to air dry

VIRUCIDAL

[This product or product name] is an effective virucide on hard, non-porous surfaces, in the presence of an organic load, against Poliovirus serotype 1 [PV-1] [ATCC VR-1562], Hepatitis B Virus, Hepatitis C Virus, Rhinovirus [ATCC VR-340] Norovirus Human Coronavirus [ATCC VR-1558], Rotavirus Strain WA, Respiratory Syncytial Virus [ATCC VR-26], Human Immunodeficiency Virus [HIV-1], Herpes Simplex Virus Type 1 [ATCC VR-539], and Influenza Virus type A₂ when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry

KILLS HIV-1, HBV and HCV ON PRE-CLEANED ENVIRONMENTAL SURFACES/OBJECTS PREVIOUSLY SOILED WITH BLOOD/BODY FLUIDS in health care settings [Hospitals, Nursing Homes] 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 Human Immunodeficiency Virus Type 1 [HIV-1] [associated with AIDS], Hepatitis B Virus [HBV], and Hepatitis C Virus [HCV]

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1, HBV, and HCV FOR SURFACES OR OBJECTS SOILED WITH BLOOD OR BODY FLUIDS

PERSONAL PROTECTION When handling items soiled with blood or body fluids, use 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 [this product or product name]

CONTACT TIME Allow surface to remain wet for 1 full minute

DISPOSAL OF INFECTIOUS MATERIALS Blood and other body fluids should be autoclaved and disposed of according to local regulations for infectious waste disposal

Note To Reviewer – These Related Optional Statements May Appear Anywhere on the Label

- Respiratory illnesses attributable to Pandemic 2009 H1N1 are caused by Influenza A virus. This product [Product Name] is a broad-spectrum hard surface disinfectant that has been shown to be effective against [Influenza A virus tested and listed on the label] and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 [formerly called swine flu]
- This product [Product Name] has demonstrated effectiveness against Influenza A virus and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 Influenza A virus
- This product [Product Name] has demonstrated effectiveness against [Influenza A virus tested and listed on the label] and is expected to inactivate all Influenza A viruses including Pandemic 2009 H1N1 [formerly called swine flu]
- Kills Pandemic 2009 H1N1 Influenza A virus [formerly called swine flu]
- Kills Pandemic 2009 H1N1 Influenza A virus

BACTERICIDAL

[This product or product name] is an effective disinfectant on hard non-porous surfaces, in the presence of an organic load, against *Escherichia coli* [E coli] O157 H7 [ATCC 35150], *Pseudomonas aeruginosa* [ATCC 15442], *Salmonella enterica* [Salmonella] [ATCC 10708], *Staphylococcus aureus* [ATCC 6538], *Streptococcus pyogenes* [Strep] [ATCC 19615], Vancomycin resistant *Enterococcus faecium* [VRE] [ATCC 51559], Methicillin resistant *Staphylococcus aureus* [MRSA] [ATCC 33591], *Klebsiella pneumonia* [ATCC 4352], *Listeria monocytogenes* [ATCC 984], *Acinetobacter baumannii* [ATCC 19606], *Campylobacter jejuni* [ATCC 29428] and *Burkholderia cepacia* [ATCC 25416] when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

TUBERCULOCIDAL

[This product or product name] is an effective disinfectant on hard non-porous surfaces, in the presence of an organic load, against *Mycobacterium bovis* [ATCC 35743], when the treated surface is allowed to remain wet for 1 minute. Allow surfaces to air dry.

FUNGICIDAL

[This product or product name] is an effective fungicide against *Trichophyton mentagrophytes* [ATCC 9533] [causative agent of Athlete's Foot Fungus] [a cause of ringworm] [a cause of ringworm of the foot], when used as directed on hard surfaces found in bathrooms, shower stalls, locker rooms, exercise facilities or other clean, hard, non-porous, surfaces commonly contacted by bare feet. The surface must remain visibly wet for 1 minute. Allow surfaces to air dry.

EFFICACY TESTS HAVE DEMONSTRATED THAT [THIS PRODUCT OR PRODUCT NAME] IS AN EFFECTIVE, VIRUCIDE, BACTERICIDE, TUBERCULOCIDE AND FUNGICIDE IN THE PRESENCE OF ORGANIC SOIL [5% BLOOD SERUM]

For surfaces that may come in contact with food, a potable water rinse is required

[This product or product name] will not harm most surfaces including stainless steel, aluminum, plastics, fiberglass, vinyl, and most painted surfaces For plastic and painted surfaces, spot test on an inconspicuous area before use Do not use on unpainted wood Not for use on people or pets

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION Causes moderate eye irritation 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

FIRST AID

IF IN EYES Hold eyes open and rinse slowly and gently with water for 15–20 minutes Remove contact lenses if present, after the first 5 minutes, then continue rinsing Call a poison control center or doctor for treatment advice

Have the product container or label with you when calling a poison control center doctor, or going for treatment For emergency information concerning this product, call the National Pesticides Information Center [NPIC] at 1-800-858-7378 seven days a week 6 30 am to 4 30 pm Pacific Time [NPIC Web site www.npic.orst.edu]

PHYSICAL OR CHEMICAL HAZARDS

Flammable Keep away from heat or open flame

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE Always store this product and all pesticides in the original container If a leaky container must be contained within another, mark the outer container to identify the contents Protect from extreme heat or cold

PESTICIDE DISPOSAL Waste resulting from the use of this product must be disposed of on site or at an approved waste disposal facility

CONTAINER DISPOSAL Nonrefillable container Do not reuse or refill this container Offer for recycling if available, or discard empty container in trash

*Note To Reviewer - The Following Additional Marketing Claims
Are Optional and May Appear Anywhere On the Label*

- disinfects [odor causing] [common] [household] [kitchen –and/or-bathroom] bacteria
- maximum cleaning, minimum effort
- easy to [carry] [use] [container] [dispensing system]
- for all [household] [institutional] surfaces
- great for clean-up at school, daycare or community center
- sanitizes [TV] [DVD] [Video Game] remote controls
- uses [x]% less plastic than other [bottles] [containers] [in the market]
- uses [x]% less packaging than similar products
- uses [x]% recycled materials in the packaging
- [packaging] made from [x]% renewable resources

*Note To Reviewer The Following Optional Warranty and
Disclaimer Statement[s] May Appear Anywhere On the Label]*

LIMITED WARRANTY AND DISCLAIMER NOTICE

The manufacturer of this product and/or it's affiliates and distributors warrant that this product conforms to the chemical description on this label and is reasonably fit for the purposes referred to in the Directions For Use and elsewhere on this label Buyer assumes all risks of use and handling which is a variance in any way with the directions herein The manufacturer makes no other express or implied warranty of fitness or merchantability In no case shall the manufacturer or the seller of this product be liable for consequential, special or indirect damages resulting from the use or handling of this product The manufacturer, distributor, and seller, and the buyer and user of this product acknowledge and accept the foregoing Limited Warranty and Disclaimer which may be varied only by agreement in writing signed by a duly authorized representative of the manufacturer

or

No warranty, either expressed or implied, is given to the usage contrary to the instructions given herein

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Note To Reviewer - The Following Table or Portions Thereof May Appear On the Printed Product Label and May Appear in Associated Marketing Materials

This Product [product name] Kills the Following Pathogens in One Minute			
Pathogen	ATCC Number	Organic Load	Kill Time
Acinetobacter baumannii	19606	5%	1 minute
Burkholderia cepacia	25416	5%	1 minute
Campylobacter jejuni	29428	5%	1 minute
Escherichia coli O157 H7 [E. coli]	35150	5%	1 minute
Klebsiella pneumonia	4352	5%	1 minute
Listeria monocytogenes	984	5%	1 minute
Methicillin resistant Staphylococcus aureus [MRSA]	33591	5%	1 minute
Pseudomonas aeruginosa	15442	5%	1 minute
Salmonella enterica	10708	5%	1 minute
Staphylococcus aureus [Staph]	6538	5%	1 minute
Streptococcus pyogenes [Strep]	19615	5%	1 minute
Vancomycin resistant Enterococcus faecium [VRE]	51559	5%	1 minute
Mycobacterium bovis [Tuberculosis]	35743	5%	1 minute
Trichophyton mentagrophytes [Athletes Foot fungus]	9533	5%	1 minute
Coronavirus	VR-1558	5%	1 minute
Hepatitis B	n/a	5%	1 minute
Hepatitis C	n/a	10%	1 minute
Herpes Simplex virus type 1	VR-539	5%	1 minute
Human Immunodeficiency virus [HIV-1] [AIDS]	n/a	10%	1 minute
Influenza virus type A2 [Flu]	n/a	5%	1 minute
Norovirus	n/a	5%	1 minute
Poliovirus	VR-1562	5%	1 minute
Respiratory Syncytial virus [RSV]	VR-26	5%	1 minute
Rhinovirus	VR-340	5%	1 minute
Rotavirus Strain WA	n/a	5%	1 minute