



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 3, 2016

Susan Stracquatano
Agent for maxill inc.
maxill inc.
c/o Delta Analytical Corp.
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: Notification per PRN 98-10 – Add Alternate Brand Name (including on label)
Product Name: Panther Disinfectant Towelette
EPA Registration Number: 88897-1
Application Date: August 16, 2016
Decision Number: 520781

Dear Stracquatano:

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) 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.

The alternate brand name “mycolio DISINFECTANT WIPES” has been added to the product record.

If you have any questions, you may contact Joe Daniels at (703) 347-8669 or via email at daniels.joseph@epa.gov.

Sincerely,

A handwritten signature in blue ink that reads "E. Miederhoff". The signature is written in a cursive style with a large, stylized initial "E".

Eric Miederhoff
Product Manager 31
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

maxill

NOTIFICATION

88897-1

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:

10/03/2016

Panther Disinfectant Towelette

[Alternate Brand Names: mycolio, mycolio DISINFECTANT WIPES]

{For only the refill pouch label :} [Refill Pouch]

{Select as applicable to marketed product & appropriate, terms may be separated by bullets, commas, "and" or "&" :}

[Tuberculocidal] [Mycobactericidal] [Virucidal[†]] [Fungicidal] [Bactericidal] [Pseudomonacidal] [Germicidal] [Tuberculocide] [Mycobactericide] [Virucide[†]] [Fungicide] [Bactericide] [Germicide]

{Select as appropriate, terms may be separated by line spacing, bullets, commas, "and" or "&" :}

[Cleans] [Disinfects] [Deodorizes] [Broad Spectrum Disinfectant] [Cleaner] [Disinfectant] [Deodorizer] [Multi-purpose Cleaner] [Great for use on Dental Chairs] [Great for use in Hospitals, Dental Offices and other Medical Settings]

ACTIVE INGREDIENTS:

n-Alkyl (50% C14, 40% C12, 10% C16)	
dimethyl benzyl ammonium chloride	0.34%
Didecyl dimethyl ammonium chloride.....	0.51%
Ethanol	6.84%
Isopropanol	13.68%

INERT INGREDIENTS: 78.63%

TOTAL: 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION

READ THE LABEL BEFORE USING

{If Precautionary Statements and First Aid are not located here, the following phrase will be used ;}

[See side [back] panel for additional Precautionary Statements.]

EPA Reg. No. 88897-1 EPA Est. No: 88897-CAN-001

{Producer/Registrant/Person for whom Produced, one of :}

[Packed for * * *] [Manufactured for [by] * * *] [Distributed by * * *] [Sold by * * *]

maxill

80 Elm Street

St. Thomas, Ontario N5R 6C8, Canada

1 800 268-8633

NET CONTENTS: ___ lbs. ___ oz.

___ [Pre-moistened] [Towelettes] [Wipes] [, ___" x ___"]

[Reorder No.] [Item No.] _____

Note: [Bracketed text] is optional/alternate text and it might not appear on the marketing label.
{Bracketed Text} is for administrative information only and will not appear on the marketing label.

PRECAUTIONARY STATEMENTS: HAZARD TO HUMAN AND DOMESTIC ANIMALS.

CAUTION: Harmful if inhaled. Do not breathe vapor. Causes moderate eye irritation. Avoid contact with eyes, or clothing. Wear protective eye wear (eye glasses and eye goggles) and gloves. Remove and wash contaminated clothing before use. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

FIRST AID:

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

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.

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 non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu)

PHYSICAL OR CHEMICAL HAZARDS: Combustible. Do not use or store near heat or open flame.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal.

Storage: Store in a cool place. Tightly close lid between uses to retain moisture.

Towelette Disposal: Do not reuse towelette [wipe]. Dispose of towelette [wipe] in trash after use. Do not flush [in toilet].

{Container Disposal, One of the following :}

{For canisters that are not intended to be refilled by consumer :}

[CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Offer empty container for recycling. If recycling is not available, discard container in trash.]

{For canisters intended to be refilled by the consumer :}

[CONTAINER HANDLING: Do not reuse or refill except as described in the directions for use. Refill only with this product [product name]. Offer unusable [broken] [cracked] container [canister] for recycling. If recycling is not available, discard container [canister] in trash.]

{For pouches containing a refill roll that is handled by consumer :}

[CONTAINER HANDLING [[PACKAGE] [POUCH] DISPOSAL]: Discard empty packaging in trash.]

{MARKETING INFORMATION}

{Select as appropriate, terms may be separated by bullets, commas, "and" or "&" :}

[Cleans] [Disinfects] [Deodorizes]

[Broad Spectrum][Cleaner] [Disinfectant] [Hospital Use] [Deodorizer] [Multi-purpose Cleaner]

[Panther Disinfectant Towelette] [[Marketing Name] Towelettes [Disinfectant Towelettes] [Hard Surface Disinfectant Towelettes] [Disinfectant Wipes] [Hard Surface Disinfectant Wipes] [Wipes]] is a [are] disposable, non-woven, single-use towelette[s]. [It is] [They] are intended for use on pre-cleaned, hard non-porous inanimate surfaces in areas where the disinfection of surfaces is required.

When used as directed [these towelettes] [these wipes] clean and disinfect hard, non-porous, non-food contact surfaces found in

{One or more of the following sites may be listed, as appropriate. The last area will be preceded with the word "and" :}

ambulances	funeral homes	operating rooms
athletic clubs	GI laboratories	offices
automobile interiors	gyms	ophthalmic centers
autopsy rooms	hair salons	paramedic units
barber shops	health clubs	pathology facilities
bathrooms	hospitals	patient care areas
beauty salons	healthcare facilities	pheresis equipment and centers
blood centers	hotels	podiatry offices
buses	human transport vehicles	police vehicles
cadaver work [processing] areas	infant care units	prisoner holding areas [lockups]
cardiac care labs	institutional facilities	prisons
cardiac catheterization labs	intensive care units	radiology centers
cardiology units	isolation rooms [units]	research laboratories
child care facilities	laboratories	respiratory care units
clean rooms	large animal care facilities	schools
clinical areas	lasik centers	skin care facilities
daycare centers	locker rooms	spas
dental facilities	long-term care facilities	surgical centers and rooms
dialysis units	medical facilities	tanning salons
drug preparation facilities	medical offices	tattoo parlors
EMS units	morgues	trailers
emergency rooms	nail care facilities	train cars
endoscopic rooms	nail salons	transport equipment
esthetician facilities	neonatal units	workout rooms
extended care facilities	newborn nurseries	areas/facilities concerned with the
food processing facilities	nursing homes	hazards of cross-contamination
(non-food contact surfaces)		from infectious microorganisms

Note: [Bracketed text] is optional/alternate text and it might not appear on the marketing label.
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When used as directed [these towelettes] [these wipes] may be used on the following hard, non-porous, non-food contact surfaces

{One or more of the following areas for use may be listed, as appropriate. The last item will be preceded with the word “and” :}

athletic/training facility surfaces	incubators	shampoo bowls
baby/infant care surfaces	infant care equipment	ship [river, ocean, sea vessel] surfaces
bassinets	(bassinets, bed railings, cribs, infant incubator-surfaces, tables, warmers (exterior surface))	showers [floors/walls]
bathing units	keyboards	sink faucets
bed rails	laminated surfaces	sinks
beds	light lens covers	small animal care surfaces
cabinets	loupes	stalls
changing tables	mats	stair chairs
commodes	manicure/pedicure tables/chairs	tables
computer keyboards [surfaces]	mannequins	tanks
counters	monitor knobs	tanning bed surfaces
curing lights	monitors	telephones,/toilets (rims, seats and exterior surfaces)
diving equipment and air packs	optical wear (excluding contact lenses)	toys
doorknobs	optical wear (excluding contact lenses)	transport van surfaces
equipment surfaces	optical wear (excluding contact lenses)	transportation equipment surfaces
eye glasses	optical wear (excluding contact lenses)	turn-out gear
eye protection devices	optical wear (excluding contact lenses)	walls
finished surfaces	optical wear (excluding contact lenses)	warmers (exterior surface)
firefighter turnout gear	optical wear (excluding contact lenses)	wet/dry suits
foot spa surfaces	optical wear (excluding contact lenses)	whirlpool surfaces
funeral home surfaces	optical wear (excluding contact lenses)	work stations
goggles	optical wear (excluding contact lenses)	wresting mats
helmets	optical wear (excluding contact lenses)	
hospitality and hotel surfaces	optical wear (excluding contact lenses)	

When used as directed [these towelettes] [these wipes] may be used on the following hard, non-porous, non-critical parts of the following items/surfaces

{One or more of the following areas for use may be listed, as appropriate. The last item will be preceded with the word “and” :}

ambulance equipment and [patient care] surfaces	medication infusion surfaces	patient stretchers
anesthesia equipment surfaces	microkeratome surfaces	patient transport surfaces
backboards	microscopes	pharmacy surfaces
blood pressure devices	morgue tables	physical therapy equipment (such as bars, chairs, empty whirlpool tanks, etc.)
breathing masks	MRI equipment surfaces	pulmonary function equipment
CPR training devices	neonatal/nursery surfaces	radiology equipment surfaces
CT equipment/ surfaces	non-critical devices	respirators
dental chairs	nursing station surfaces	respiratory care equipment surfaces
dental equipment surfaces/devices	OB [obstetrical equipment] surfaces	respiratory therapy equipment
dialysis machine surfaces	occupational therapy devices	skin care equipment/surfaces
EMS equipment/work surfaces	office fixtures	spirometers
ER surfaces	OR lights	stretchers
examination tables	OR surfaces	surgical equipment surfaces
gonio lenses	OR tables	surgical microscopes
hard cervical collars/braces	ophthalmic equipment surfaces/devices	tattooing equipment surfaces/devices
instrument stands	oxygen hoods	ventilators
Isolettes®	oxygen tents	wheel chairs
kidney machines	patient bed surfaces	X-ray equipment/surfaces
laboratory equipment/surfaces	patient care devices	devices/surfaces potentially contaminated with disease-causing microorganisms
mayo stands	patient care equipment surfaces	
medical equipment surfaces/devices	patient examination tables	

When used as directed [these towelettes] [these wipes] may be used on the following hard, non-porous non-food contact materials

{One or more of the following areas for use may be listed, as appropriate. The last area will be preceded with the word “and” :}

glass	clear plastic	baked painted surfaces
metal	stainless steel	laminated surfaces and other similar surfaces
Plexiglas®	brass	powder painted coated surfaces
plastics (i.e., polycarbonate, and polypropylene, polyvinylchloride polystyrene, and non-porous vinyl)	chrome	Formica®
	copper	glazed tile
	acrylic	

[If you are uncertain as to the material composition of your item, confirm with the manufacturer before proceeding.]

{If applicable :}

[For plastic and painted surfaces, spot test on an inconspicuous area before use.]

Note: [Bracketed text] is optional/alternate text and it might not appear on the marketing label.
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{Microorganisms must be used with their respective contact times}

Organisms Controlled/Contact Times[†]

When used as directed on pre-cleaned hard, non-porous non-food contact surfaces, [[Panther Disinfectant Towelette] [Marketing Name] Towelettes [Disinfectant Towelettes] [Hard Surface Disinfectant Towelettes] [Disinfectant Wipes] [Hard Surface Disinfectant Wipes] [Wipes]] is [are] [virucidal] [bactericidal] [fungicidal] [tuberculocidal] against [the following organisms] at *contact time*

1-minute contact time [Viruses]

*Human Immunodeficiency virus 1 (HIV-1)**

2-minutes contact time [Viruses]

Influenza A virus (H3N2)

*Duck Hepatitis B virus (Surrogate for Human Hepatitis B Virus)**

*Bovine Viral Diarrhea virus (Surrogate for Human Hepatitis C Virus)**

3-minutes contact time [Viruses]

Poliovirus Type 1

2-minutes contact time [Bacteria]

Salmonella enterica [ATCC 10708]

Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51299]

Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33592]

3-minutes contact time [Bacteria]

Pseudomonas aeruginosa [ATCC 15442]

Staphylococcus aureus [ATCC 6538]

3-minutes contact time [Tuberculosis]

Mycobacterium bovis BCG (Tuberculosis)

3-minutes contact time [Fungi]

Trichophyton mentagrophytes

When used as directed on pre-cleaned hard, non-porous non-food contact surfaces, [[Panther Disinfectant Towelette] [Marketing Name] Towelettes [Disinfectant Towelettes] [Hard Surface Disinfectant Towelettes] [Disinfectant Wipes] [Hard Surface Disinfectant Wipes] [Wipes] disinfect[s] [the following microorganisms with a] *contact time*

1-minute contact time

Human Immunodeficiency virus 1 (HIV-1)

2-minutes contact time

Salmonella enterica [ATCC 10708]

Vancomycin Resistant *Enterococcus faecalis* (VRE) [ATCC 51299]

Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33592]

Influenza A virus (H3N2),

Duck Hepatitis B virus (Surrogate for Human Hepatitis B Virus)

Bovine Viral Diarrhea virus (Surrogate for Human Hepatitis C Virus)

3-minutes contact time

Mycobacterium bovis BCG (Tuberculosis),

Pseudomonas aeruginosa [ATCC 15442]

Staphylococcus aureus [ATCC 6538]

Poliovirus Type 1

Trichophyton mentagrophytes

DIRECTIONS FOR USE

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

Not for personal cleansing. This product is not a baby wipe. Do not use on contact lenses. [Do not flush [in the toilet].]

{The following paragraph will be included when the marketing label references health care use :}

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

{For product marketed in a dispensing canister that may be refilled only by the consumer :}

To start the feed through the lid:

1. Unscrew entire lid from the canister and remove the protective seal from the canister.
2. Pull up a corner of the first [towelette] [wipe] from the center of the roll and push 1 inch through the hole in the lid. DO NOT PUSH FINGER THROUGH THE HOLE.
3. Replace lid tightly on the canister.
4. Lift the flip-top and pull out the [towelettes] [wipes] one at a time.
- 5 Document the date opened on the sticker that is provided.
6. Ensure lid remains closed between uses to prevent moisture loss.

This container may be refilled by the consumer with [Panther Disinfectant Towelettes] [Marketing Name] Towelettes [Disinfectant Towelettes] [Hard Surface Disinfectant Towelettes] [Disinfectant Wipes] [Hard Surface Disinfectant Wipes] [Wipes] Refill Pouch. Refer to further instructions on the label of the refill pouch.

{For product marketed in a non-refillable refill pouch :}

Placing the contents of the Refill Pouch into a dispenser:

1. Open empty canister lid.
2. Open Refill Pouch [by cutting the top of the pouch] and remove saturated [towelettes] [wipes].
3. Place saturated towelettes in empty canister including excess liquid in the bottom of the pouch.
4. Replace canister lid.
5. Write the new lot number / expiry date from the pouch on the sticker provided.
6. Place the sticker on top of the old lot number / expiry date on the canister. Remove previous stickers if present.

[CLEANING AND DISINFECTING:

Pre-clean the surface of gross debris. [Use one [Panther Disinfectant Towelette] [[Marketing Name] [wipe] [towelette]] to [deodorize and] pre-clean the surface of gross debris. Discard.] Pull [a] [another] [wipe] [towelette] from the [dispenser] [canister] and thoroughly wipe [wet] the surface. [Treated surface must remain visibly wet for the appropriate time indicated for the purpose intended.] {or} For broad spectrum disinfection, allow the surface to remain wet for 3 minutes. Use additional towelettes if needed to ensure the correct wet contact time. [Wipe the surface dry.] {or} [Rinse surface and [wipe] [allow to air] dry.] Change the [wipe] [towelette] after each use [application].]

*This product effectively kills [*Human Immunodeficiency virus 1 (HIV-1)*,] [Hepatitis B Virus (HBV),] [[and] Hepatitis C Virus (HCV)] 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 of inanimate surfaces/objects with blood/body fluids, and in which the surfaces/objects can be associated with the potential for transmission of [HIV-1], [HBV,] [[and] [HCV].

Special Instructions for Cleaning and Decontamination Against [HIV-1,] [HBV,] [[and] HCV] of Surfaces or Objects Soiled With Blood or Body Fluids:

Personal Protection: When using this disinfecting towelette, wear appropriate barrier protection such as disposable protective gloves, protective gown, face mask and eye covering.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of this disinfecting towelette. A [Panther Disinfectant Towelette] [[Marketing Name] [towelette] [wipe]] can be used for this purpose.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1. Use a 2 minute contact time for HBV and HCV.

Disposal of Infectious Materials: Cleaning materials used that may contain blood or other body fluids should be autoclaved and disposed of in accordance with Federal, State and local regulations for infectious materials disposal.

[[Batch] [Lot] No. _____]

[SDS No. _____]

[Questions? Call _____, [__ am – __ pm [Eastern] [Central] [Mountain] [Pacific] Time
Weekdays] [24 hours/ 7 days a week]]

[For Emergencies, call _____]

[www._____.____]

Made in Canada

{One of the following stickers is provided with each canister and refill pouch :}



Note: [Bracketed text] is optional/alternate text and it might not appear on the marketing label.
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