



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 4, 2021

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

Subject: PRIA Label Amendment – Add SARS-CoV-2 and other organism claims
Product Name: Panther Disinfectant Towelette
EPA Registration Number: 88897-1
Received Date: May 7, 2021
Action Case Number/Decision Number: 00300747

Dear Jaqueline Sumski:

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. 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) 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, 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 Assurance.

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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, you may contact Joseph Daniels via email at Daniels.joseph@epa.gov.



Eric Miederhoff

Product Manager 31

Regulatory Management Branch I

Antimicrobials Division (7510P)

Office of Pesticide Programs

Enclosure

[maxill]

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][Disinfectant
and Sanitizer] [Deodorizer] [Multi-purpose Cleaner] [Great for use on Dental Chairs▲] [Great for use in
Hospitals, Dental Offices and other Medical Settings▲] [JUMBO Size [Wipes] [Towelettes]]

▲ on hard, non-porous surfaces only

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

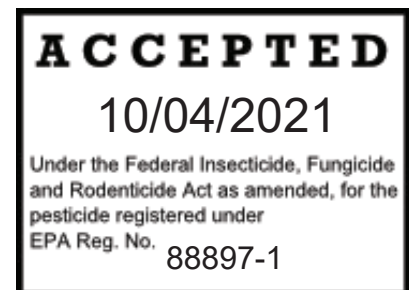
maxill
80 Elm Street
St. Thomas, Ontario N5R 6C8, Canada
1 800 268-8633

NET CONTENTS: ___ lbs. ___ oz.

___ [Pre-moistened] [JUMBO Size] [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 [,and sanitize] 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.
{Bracketed Text} is for administrative information only and will not appear on the marketing label.

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

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	surfaces
dialysis machine surfaces	occupational therapy devices	respiratory therapy equipment
EMS equipment/work surfaces	office fixtures	skin care equipment/surfaces
ER surfaces	OR lights	spirometers
examination tables	OR surfaces	stretchers
gonio lenses	OR tables	surgical equipment surfaces
hard cervical collars/braces	ophthalmic equipment surfaces/devices	surgical microscopes
instrument stands	oxygen hoods	tattooing equipment
Isolettes®	oxygen tents	surfaces/devices
kidney machines	patient bed surfaces	ventilators
laboratory equipment/surfaces	patient care devices	wheel chairs
mayo stands	patient care equipment surfaces	X-ray 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.]

{Microorganisms must be used with their respective contact times}

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.

{Reader's Note: Marketplace label will include organism list in the format below OR the format listed on the following page.}

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)**
SARS-CoV-2 [(Virus that causes COVID-19)]

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 [Fungi]

Trichophyton interdigitale

30-seconds, Non-Food Contact Sanitizer

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 an effective sanitizer in 30 seconds against:

Staphylococcus aureus [ATCC 6538]
Klebsiella pneumoniae [ATCC 4352]

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)

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] disinfect[s] [the following microorganisms with a] *contact time*:

1-minute contact time

Human Immunodeficiency virus 1 (HIV-1)
SARS-CoV-2 [(Virus that causes COVID-19)]

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)
Trichophyton interdigitale

3-minutes contact time

Mycobacterium bovis BCG (Tuberculosis),
Pseudomonas aeruginosa [ATCC 15442]
Staphylococcus aureus [ATCC 6538]
Poliovirus Type 1

30-seconds contact time, Non-Food Contact Sanitizer

Staphylococcus aureus [ATCC 6538]
Klebsiella pneumoniae [ATCC 4352]

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.
{If the distributor includes a calendar sticker with the product}
5. [Document the date opened on the sticker that is provided.]
5. {or} 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.
{If the distributor includes a calendar sticker with the product}
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, SANITIZING & DISINFECTING

Pre-clean all surfaces prior to disinfecting or sanitizing.

To Sanitize: Using this product, wipe the surface using enough wipes for surface to remain visibly wet for 30 seconds. Then wipe the surface dry.

To Disinfect: Using this product, wipe the surface using enough wipes for surface to remain visibly wet for the entire contact time required for the intended purpose (see ORGANISMS CONTROLLED / CONTACT TIMES[†]). For broad spectrum disinfection, allow the surface to remain visibly wet for 3 minutes. Then wipe the surface dry.

*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.

{As Applicable, per **GUIDANCE TO REGISTRANTS: PROCESS FOR MAKING CLAIMS AGAINST EMERGING VIRAL PATHOGENS NOT ON EPA-REGISTERED DISINFECTANT LABELS**. The statements will NOT appear on marketed (final print) product labels and will only be made through the communications outlets listed in the **Guidance**.}

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
- Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an...</i>	<i>...following the directions for use for the following organisms on the label:</i>
Enveloped virus	Poliovirus Type 1
Large, non-enveloped virus	Poliovirus Type 1

[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.

{AND/OR}

[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.

[[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

[Optional Sticker Calendar]

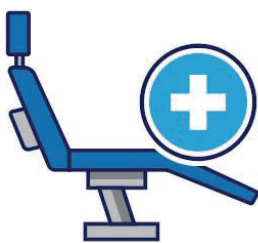
{The following sticker may be provided with each canister and refill pouch :}



{Optional Graphic}

{The following may be used as a sticker or graphic with each canister and refill pouch :}

{Reader's Note: The cleaning protocol refers to the cleaning instructions recommended by the dental chair manufacturers. These cleaning instructions are provided with the chair instructions, and call for cleaning the chair after disinfection to remove disinfectant residue/build-up. Maxill's website will include information on the care for dental chairs, as well as instruct users to refer to manufacturer instructions. The graphic is meant to highlight the fact that clients should take note of their chair manufacturer's cleaning instructions when using a disinfectant such as this product.}



Cleaning Care for Dental Chairs

IN ADDITION TO DISINFECTING, A CLEANING PROTOCOL IS REQUIRED
BY THE CHAIR MANUFACTURER

Call 1-855-462-9455 for more information
www.maxill.com/us/chairecare