



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Antimicrobials Division (7510P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

88897-2

Date of Issuance:

8/20/19

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Panther Disinfectant

Name and Address of Registrant (include ZIP Code):

Jeff Jones
 Maxill, Inc
 Delta Analytical Corporation
 12510 Prosperity Drive, Suite 160
 Silver Spring, MD 20904

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials 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 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 is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. 7Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Zeno Bain, Product Manager 33
 Regulatory Management Branch I
 Antimicrobials Division (7510P)
 Office of Pesticide Programs

Date:

8/20/19

You are required to comply with the data requirements described in the DCIs identified below:

- a. ADBAC GDCI-069105-30882
- b. DDAC GDCI-069149-30869

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>

2. Make the following label changes before you release the product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 88897-2.”
3. Submit one copy of the final printed label for the record before you release the product for shipment.

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.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 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. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 07/18/2018

If you have any questions, please contact Terria Northern by phone at 703-347-0265, or via email at northern.terria@epa.gov.

Enclosure: Accepted label



[maxill]
Panther DISINFECTANT

{For only the refill jug :} [Refill Jug]

{For only the sprayer bottle :} [Spray]

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

[Tuberculocidal] [Virucidal[†]] [Bactericidal] [Fungicidal] [Germicidal]

[Tuberculocide] [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- 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 inc.

80 Elm Street

St. Thomas, Ontario N5R 6C8, Canada

1-800-268-8633 [www.maxill.com]

NET CONTENTS: ___ FL. OZ. [____][Gal.][Gallons]] [____][Qt.][Quarts]]

{For the refill jug:} [[BONUS!] [25]% more than 1 Gallon!]

[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: Causes moderate eye irritation. Avoid contact with eyes, or clothing. Harmful if inhaled. Avoid breathing vapor or spray mist. Wear gloves, and eye glasses or eye goggles. 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 use.

FIRST AID:

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.

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 treatment advice. Have the product container or label with you when calling a poison control center, doctor, or going for treatment. For medical emergencies, call the poison control center at 1-800-222-1222. 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.]

{Container Disposal, One of the following :}

{For containers 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 packages / spray bottles 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][Panther DISINFECTANT][ABN]. Offer unusable [broken] [cracked] container for recycling. If recycling is not available, discard container 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] [ABN] is intended for use on pre-cleaned, hard non-porous inanimate surfaces in areas where the disinfection of surfaces is required.

When used as directed [Panther DISINFECTANT] [ABN] cleans and disinfects 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	
food processing facilities (non-food contact surfaces)	nursing homes	

When used as directed [Panther DISINFECTANT] [ABN] may be used on hard, non-porous, non-food contact surfaces of the following*

{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	wrestling mats

* Not to be used on unfinished wood or other porous surfaces

When used as directed [Panther DISINFECTANT] [ABN] may be used on 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
external surfaces of CPAP masks and units	neonatal/nursery surfaces	radiology equipment surfaces
CPR training devices	non-critical devices	respirators
CT equipment/ surfaces	nursing station surfaces	respiratory care equipment surfaces
dental chairs	occupational therapy devices	respiratory therapy equipment
dental equipment surfaces/devices	office fixtures	skin care equipment/surfaces
dialysis machine surfaces	OR lights	spirometers
EMS equipment/work surfaces	OR surfaces	stretchers
ER surfaces	OR tables	surgical microscopes
examination tables	ophthalmic equipment surfaces/devices	tattooing equipment surfaces/devices
gonio lenses	oxygen hoods	ventilators
hard cervical collars/braces	oxygen tents	wheel chairs
instrument stands	patient bed surfaces	X-ray equipment/surfaces
Isolettes®	patient care devices	
kidney machines	patient care equipment surfaces	
laboratory equipment/surfaces	patient examination tables	
mayo stands		
medical equipment surfaces/devices		

* Not to be used on unfinished wood or other porous surfaces

When used as directed [Panther DISINFECTANT] [ABN] 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][surface][device], confirm compatibility 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.
{Bracketed Text} is for administrative information only and will not appear on the marketing label.

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

1-minute contact time

Human Immunodeficiency virus type 1 (HIV-1)*

Duck Hepatitis B Virus [(DHBV)] (Surrogate for Human Hepatitis B Virus)* [(HBV)]

Bovine Viral Diarrhea Virus [(BVDV)] (Surrogate for Human Hepatitis C Virus)* [(HCV)]

Rotavirus [ATCC VR-2018]

Human Coronavirus [ATCC VR-740]

Avian Influenza A (H3N2) Reassortant virus [ATCC VR-2072]

Herpes simplex virus type 1 [ATCC VR-733]

Herpes simplex virus type 2 [ATCC VR-734]

3-minute contact time

Mycobacterium bovis BCG (Tuberculosis),

Pseudomonas aeruginosa [ATCC 15442]

Staphylococcus aureus [ATCC 6538]

Salmonella enterica [ATCC 10708]

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

Methicillin Resistant *Staphylococcus aureus* (MRSA) [ATCC 33591]

Adenovirus type 5 [ATCC VR-5]

Feline calicivirus [(Surrogate for Human Norovirus)] [ATCC VR-782]

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 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 sprayer that may be refilled only by the consumer :}

Setting up the Sprayer:

1. Remove the cap and bottle seal. Discard.
2. Insert and secure the provided sprayer to the bottle.
3. Keep upright.

This container may be refilled by the consumer with [Panther DISINFECTANT] [ABN] sold in jug quantities. Refer to further instructions on the label of the jug.

{For product marketed in a non-refillable jug :}

Placing the Contents of the Refill Jug into an Empty Sprayer:

1. Remove the cap and bottle seal. Discard seal and retain the cap.
2. Pour product from the refill jug into the empty and clean sprayer bottle, being careful not to overfill the sprayer bottle.
3. Insert and secure the sprayer to its bottle.
4. Secure the retained cap snugly to the refill jug.

[CLEANING AND DISINFECTING: Hard, non-porous surfaces

Remove gross debris and pre-clean the surface prior to disinfection. [Gently] spray the surface with [Panther DISINFECTANT] [ABN] to [deodorize and] pre-clean the surface of gross debris. Using a disposable [cloth][towel], clean the surface. Discard. Spray [Panther DISINFECTANT] [ABN] 6 – 8 inches from the surface, thoroughly wetting area to be disinfected. [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. Spray additional product on the surface if needed to ensure the correct wet contact time. [Wipe the surface dry.] {or} [Rinse surface and [wipe] [allow to air] dry.]

{As applicable, for Blood Borne Pathogens listed on the label:}

*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: 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.

Contact Time: Allow surface to remain wet for 1 minute to kill HIV-1, HBV and HCV.

Disposal of Infectious Materials: Dispose of contaminated materials 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	Adenovirus type 5 [ATCC VR-5]
Large, non-enveloped virus	Feline calicivirus (Surrogate for Human Norovirus), Strain: F9, (ATCC VR-782)

[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. _____]

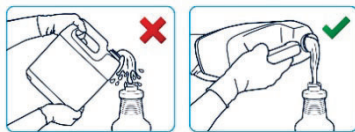
[SDS No. _____]

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

[For Emergencies, call _____]

[Made in Canada]

{Optional Graphic – refill jug}



{Optional Graphic}

{The following may be used as a sticker or graphic with each spray bottle or refill jug :}

{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

Call 1-855-462-9455 for more information

www.maxill.com/us/chairecare