

70467-3

2/7/2014

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

FEB 7 2014

OFFICE OF
CHEMICAL SAFETY
AND POLLUTION
PREVENTION

Kruti Dhyani
Micrylium Laboratories
5000-M Dufferin Street
Toronto, Canada M3H 5T5

Subject: **BioSURF**
EPA Registration No. 70467-3
Application Date: 9/10/2013
Receipt Date: 9/19/2013

Dear Ms. Dhyani:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3 (c) 7 A as amended, is acceptable with conditions.

Proposed Amendment:

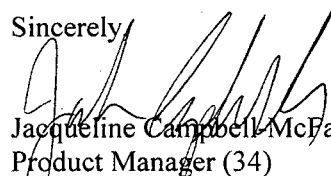
- Addition of Human Immunodeficiency Virus (HIV) and Hepatitis B Virus (HBV) claims

General Comments

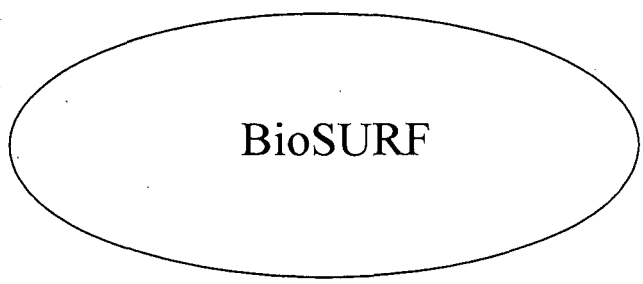
A stamped label is enclosed for your records. The efficacy review is also enclosed. This labeling supersedes all previously accepted labeling. The next label printing of this product must use this labeling unless subsequent changes have been approved. You must submit one (1) copy of the final printed 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 have any questions concerning this letter, you may contact me by telephone at 703-308-6416 or by email at Campbell.Jacqueline@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely


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

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Net Contents:

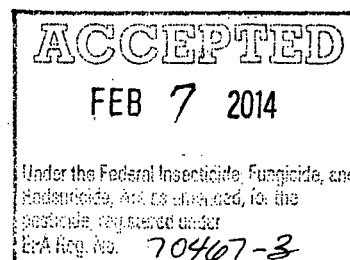
EPA Registration Number 70467-3
EPA Establishment 070467-CAN-001

Micrylium
ISO 13485: 2003

Hospital Hard Surface Disinfectant

BioSURF is a ready to use hard surface disinfectant for nonporous surfaces • One Step
[For use on hard, non-porous [imaging] [equipment] surfaces]

Active Ingredients	
Ethanol	70.5%
Chlorhexidine Gluconate	0.2%
<u>Other Ingredients</u>	29.3%
Total	100.0%



Tuberculocidal - Canine Parvovirucidal
Pseudomonacidal - Fungicidal

CAUTION

READ PRECAUTIONS ON BACK PANEL • KEEP OUT OF THE REACH OF CHILDREN

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{Administrative note: any language which appears between { } and is italicized will NOT appear on final printed labels. Any language that appears between [] is considered interchangeable language which may appear on final printed labeling}

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BioSURF

[Sprays On Blue Turns Clear!]

Aldehyde • NPE • Phenol Free

BioSURF is a ready to use environmental hard surface disinfectant for nonporous surfaces.
[Restrooms • Schools • The Office • The Gym • At Home • Dental Clinics • Spas • Hospitals]
[BioSURF will not stain: Cotton • Nylon • Rayon • Silk • Polyester]

Directions for use

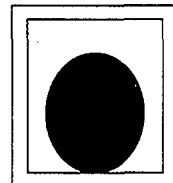
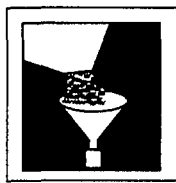
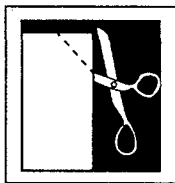
It is a violation of Federal law to use this product in a manner inconsistent with its labeling. BioSURF kills Tuberculosis (*Mycobacterium bovis* BCG) and is Virucidal (Canine parvovirus CPV -265) in [one minute] [60 seconds] in the presence of 5% bioburden [organic matter]. [BioSURF kills *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Salmonella enterica* (*formally choleraesuis*) in 20 seconds in the presence of 10% bioburden.] [BioSURF kills *Trichophyton mentagrophytes* in 10 seconds in the presence of 10% bioburden [organic matter]]. To effectively kill bacteria, fungi and inactivate canine parvovirus use BioSURF.

{Text/or refill package}

Remove trigger from 24 fl. oz. spray bottle. Cut the 16.9 fl. oz. refill pouch along the dotted line with scissors. Use a clean funnel to fill or refill bottle. Replace the trigger and rinse funnel.

BioSURF [This product] [is to] [can] be used on countertops [and] metal surfaces [and toilet exteriors]. [May be used on wheelchairs, metal bed frames and exteriors of toilets.] [BioSURF may be used on nonporous hard surfaces (imaging equipment, metal, glass, acrylic, and porcelain)]. Spray all areas with a light mist. Maintain wetness for [one minute] [60 seconds] [to kill *Mycobacterium bovis* BCG and Canine parvovirus CPV-265] [.] [Maintain wetness for 20 seconds to kill bacteria and 10 seconds to kill fungi.] [Blue color disappears,] [then] wipe [away germs] with [disposable paper towel[s]][including towelette] [or tissue] [or "Le Cloth TMtowelettes].

This product is not 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.



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Micrylium Laboratories
Professional Disinfection
www.micrylium.com
3309 Filmore Street, Suite A
San Francisco, CA 94123
1-800-489-8868

Precautionary Statements Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco or using the toilet.

PHYSICAL OR CHEMICAL HAZARDS: Flammable. Keep away from heat or open flame. Keep out of the reach of children. DO NOT use on alcohol sensitive materials such as hot plastic casings, acrylic paint, styrene or disposable plastic items. Do not apply this product in or on electrical equipment due to the possibility of shock hazard.

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. Call a Poison Control Center or doctor for treatment advice. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-489-8868 for emergency medical treatment information.

STORAGE & DISPOSAL:

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

PESTICIDE STORAGE: Do not store near open flame, at elevated temperature or in intense light.

PESICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING:

{Nonrefillable Containers}: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

{Refillable Containers}: Refillable container. Refill this container with [this brand or brand name] pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. Rinse thoroughly and dispose of any packaging materials in domestic waste. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

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{The descriptive terms below are to be used, as applicable, depending on the microorganisms listed in the Effective Against section}

[Bactericidal] [Virucidal] [Fungicidal] [Tuberculocidal]

[Healthcare Disinfectant/Decontaminant Cleaner]

[Dental Office Disinfectant/Decontaminant Cleaner]

[Hospital Disinfectant/Decontaminant Cleaner]

[Cleaner and Disinfectant in One]

[Salon Disinfectant/Decontaminant Cleaner]

[Barber Disinfectant/Decontaminant Cleaner]

[Spa Disinfectant/Decontaminant Cleaner]

[Veterinary Disinfectant/Decontaminant Cleaner]

[Clipper Blade Disinfectant/Decontaminant Cleaner]

[Disinfectant/Decontaminant Cleaner]

[1 Step Germicidal Spray]

[One Step Germicidal Spray]

[Surface Disinfectant/Decontaminant Cleaner]

[[Kitchen*** and Bath Solution] [for Hard, Non-porous Surfaces]]

[Cleans, Deodorizes and Kills Common Household Germs]

[One Step Disinfectant Cleaner]

[School/University Disinfectant/Decontaminant]

[Health Club Disinfectant/ Decontaminant]

Net Contents:

x [[Gallon] [gal]] [[Ounce] [oz.]] [[Fluid Ounce] [fl. oz.]] / x [[Liter] [L]] [[Milliliters] [ml]] [Net Weight x lbs. / x k g]

[Biosurf is available in the following packaging [configurations]:

2.5 L/0.66 gallon bottles

3 L/0.8 gallons refill dispenser box

5 L/1.32 gallons refill dispenser box

9.5 L/2.5 gallon canister/drum

60 ml/2 oz. bottles

710 ml/24 oz. bottles

950 ml / 32 oz. bottles

500 ml/16.9 oz. pouch

[This product has demonstrated effectiveness against the following organisms:]

[EFFECTIVE AGAINST]

[Mycobacterium bovis (TB) in 60 seconds] [(BCG)]

[Staphylococcus aureus in 20 seconds] [ATCC 6538]

[Pseudomonas aeruginosa in 20 seconds] [ATCC 15442]

[Salmonella enterica in 20 seconds] [ATCC 10708]

[Trichophyton mentagrophytes in 10 seconds] [ATCC 9533]

[Canine Parvovirus in 60 seconds] [CPV-265]

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[BioSurf is a ready to use one-step surface disinfectant cleaner for use on hard, non-porous surfaces. Biosurf is also a multi-purpose disinfectant/decontaminant cleaner for use on hard, non-porous inanimate surfaces.]

Recommended for use in [health care settings such as [hospitals] [hospital operating rooms] [emergency departments] [emergency medical settings] [medical related facilities] [ambulatory surgical centers] [ambulatory surgery centers (ASC)] [surgical centers] [sun / centers] [surgical suites] [out-patient surgical centers (OPSC)] [endo suites] [endoscopy centers] [GI suites] [GI centers] [sterile processing departments] [central services department] [isolation areas] [neonatal units] [anesthesia] [catheterization Laboratory] [CCU] [ICU] [Central Supply] [laboratories] [clinics] [patient care areas] [nursing homes] [ophthalmic offices] [home health care] [hospices] [isolation areas] [laboratory] [laundry rooms] [Neonatal Intensive Care Units (NICU)] [Newborn nursery] [nursing homes] [ophthalmic and optometric facilities] [eye surgical centers] [Orthopedics] [out-patient surgical centers] [patient care areas] [pediatrics] [Pediatric Intensive Care Units (PICU)] [physical therapy] [Physicians' offices] [Radiology] [Recovery rooms] [Rehabilitation] [Respiratory Therapy] [Schools] [Transport vehicles] [buses] [cruise ships] [drug preparation rooms] [pharmacy cleanrooms] [clean rooms] [X-Ray] [dialysis centers] [donation centers (blood, plasma, semen, milk, apheresis)] [dental offices] [dental operatories] [animal care facilities] [veterinary facilities] [kennels] [animal dental operator] [beauty salons] [salon settings] [manicure salons] [skin care salons] [tattoo parlors] [barber shops] [tanning salons] [emergency vehicles] [ambulances] [Emergency Rooms] [ER] [police and fire vehicles] [health club facilities] [kitchens***] [food preparation areas***] [bathrooms] [daycare centers] [correctional facilities] [prisoner detention facilities] [jails] [prisons] [morgues] [prisoner lockups][mortuaries] [cadaver processing areas] [funeral homes] [laundry rooms] [pet areas] and other critical care areas where control of cross contamination between treated surfaces is important. [Use on hard non-porous surfaces and equipment listed on this label, made of stainless steel, plastic, Formica, and glass.]

{Listing of at least one of the following equipment/instruments/hard, non-porous surfaces on production labels are required. The last equipment/instrument/hard, non-porous surface listed will be preceded with the word "and".}

BioSURF will effectively clean and disinfect in one-step, when used as directed, such items as [interior and exterior surfaces of infant incubators, bassinets, cribs and warmers] [infant/child care equipment surfaces] [diaper changing stations] [baby cribs] [diaper pails] [toys***] [high chairs] [isolettes] [lab equipment and surfaces] [diaper pails] [operating room tables and lights] [slit lamps] [laboratory equipment and surfaces] [physical therapy (PT) equipment surfaces] [exterior surfaces of dialysis machines] [patient monitoring equipment] [patient support equipment] [patient delivery equipment] [stretchers] [wheelchairs] [walkers] [stethoscopes] [spine back boards] [KED] [Kendrick Extrication Device] [ambulance equipment surfaces] [eye glasses (do not use on contact lenses)] [loupes] [bed railings] [hard, non-porous exterior surfaces of ultrasound transducers or probes] [exam tables] [gurneys] [defibrillators] [resuscitators] [IV poles] [dental unit instrument trays] [operator light switches] [exterior surfaces of amalgamators and dental curing lights] [exterior surfaces of anesthesia machines and respiratory therapy equipment] [exterior surfaces of diagnostic equipment] [external surface of SilkPeel™ with Dermalinfusion™] [workstations] [dental countertops] [dental chairs] [non-porous dental impression material] [dental impression trays] [exterior surface of dental equipment tubing] [exterior surface of dental equipment lines] [exterior surfaces of dental operatories] [digital x-ray sensors] [digital phosphor plates] [dental curing lights] [dental intra-oral cameras***] [exterior surfaces of endodontic equipment, such as apex locators, pulp testers and motors] [stools]

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[counters] [dental unit instrument trays] [endodontic equipment such as apex locators] [animal cages] [Veterinary care surfaces] [nail/hair care implements] [tanning beds] [hairdryers] [hairclippers] [shears] [razors] [hair cutting implements] [clipper blades] [salon surfaces] [scissors] [combs] [brushes] [manicure tables] [manicure implements] [washable nail files] [hair rollers] [animal cages] [non-food contact surfaces] [exterior surfaces of refrigerator units***] [exterior surfaces of appliances such as refrigerators, microwaves, food processors and stoves***] [cafeteria trays***] [dining tables***] [sinks***] [counter tops***] [food service countertops] [food serving trays] [vanity tops***] [tiles***] [floors] [walls] [handrails] [door knobs] [bed railings] [tables] [chairs] [faucets] [bathroom fixtures] [exterior toilet surfaces] [bathing units] [bathtubs] [shower stalls] [cabinets] [shampoo bowls] [garbage cans] [external surface of computers] [external surface of keyboards] [external surface of computer mouse] [external surface of fax machines] [filing cabinets] [filing doors] [filing handles] [headsets] [trash cans] [carts] [chairs] [baskets] [grocery carts] [shopping carts] [hard non-porous surface weight-lifting surfaces] [drained whirlpool tank surfaces] [cabinets] [lights] [telephones] which are made of plastic (i.e., polycarbonate, polypropylene, polyvinylchloride, polystyrene), and use sites listed on this label consisting of non-porous vinyl, stainless steel, painted surfaces, Plexiglas®, Formica® and glass.] [Bathroom(s) or public restrooms] [Basins] [Bathtubs] [Bathroom fixtures] [Countertops] [Handles] [Hampers] [Handrails] [Shower stalls] [Showers] [Sinks] [Glazed tiled walls] [Glazed tiles] [Toilet] [Toilet handle] [Toilet rim] [Toilet seats] [Tank] [And other exterior surfaces of] [Urinals] [Exterior surfaces of] and [vanity tops] [and other non-porous surfaces listed on this label.] [Transport vehicles] [School buses] [Fire trucks] [Police cars] [Hard non-porous surfaces of vehicles including steering wheel, hard plastic or metal flooring, seats, and walls] [Sleep Apnea devices] [Dental impressions dentures] [Orthodontic appliances] [Mouth guards] [Bag pipes] [Respirators].

[FOR PRECLEANING NON-INSTRUMENT SURFACES PRIOR TO DISINFECTION:

Remove gross filth and heavy soil loads. Spray BioSURF directly onto surface. Wipe surface using a disposable paper towel] [or "Le Cloth™ towelettes].

{The following statement is to be included on production labels when food contact areas or surfaces are listed.}

[***A thorough rinse with potable water is required for surfaces in direct contact with food or mouth.]

{The following HIV/HBV instructions are to be included on production labels when claims against HIV or HBV are listed.}

BIOSURF EFFECTIVELY KILLS [HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1),] [AND] [HEPATITIS B VIRUS (HBV),] ON 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] SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST [HIV-1,] [AND] [HBV,] OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUID:

Personal Protection: Wear appropriate barrier protection such as protective gloves, gowns, masks and eye Coverings.

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Cleaning Procedure: 1 step disinfectant. Spray BioSURF directly on the soiled or the required surface. Wipe surface using Le Cloth™ towelettes or disposable paper towels

Contact Time: A contact time of 1 minute is required for HIV-1 and HBV. This contact time will not be sufficient for some of the organisms listed on the label. Refer to label for contact times against other organisms.

Infectious Materials Disposal: Cleaning materials used that may contain blood or other bodily fluids must be autoclaved and/or disposed of in accordance with local regulations for infectious materials disposal.

{The following paragraph will be included in its entirety when the production 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 preclean or decontaminate critical or semi-critical medical devices prior to sterilization/high-level disinfection.]

OPTIONAL CLAIMS AND DESCRIPTORS

[Cleans and disinfects in one-step]

[An effective method to clean against odor-causing organisms on hard, non-porous surfaces listed on this label]

[Cleans]

[Cleans and disinfects]

[For cleaning and disinfecting dental impressions]

[Leaves bathroom fresh and clean in [just] 1 minute]

[Leaves [bathroom] [office] clean [and disinfected] [and smelling fresh]

[Multi-purpose cleaner]

[Perfect for cleaning [and disinfecting] around the toilet.]

[This product is] [Quick] [and easy] [and convenient] [way to clean] [and disinfect]

[Quick and easy way to clean [and disinfect] [bathroom] [or exterior toilet surfaces] [hard, non-porous surfaces]] [So] [surfaces are more than [just] [clean]

[Kills] [germs] [or bacteria] [while it cleans] [that cause odor]

[60 seconds kill time]

[60 seconds contact time]

[Always ready-to-use]

[An effective method to deodorize and disinfect against odor-causing organisms on hard non-porous surfaces]

[An effective way to disinfect hard, non-porous environmental surfaces]

[Antibacterial]

[Antimicrobial]

[Antibacterial & Antimicrobial]

[Bleach-free formula]

[Can help reduce the risk of cross contamination on treated surfaces]

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[Clean and disinfect hard, non-porous surfaces easily]
 [Convenient]
 [Convenient, quick and easy cleaning all around [the office] [business] [workplace]], home
 [Use to] [Deodorize hard, non-porous surfaces]
 [Deodorizes, and kills common household germs]
 [Disinfect external surfaces of ultrasound transducers]
 [Disinfects external surface of headsets and telephones]
 [Disinfects and deodorizes in 60 seconds]
 [Disinfects hard non-porous environmental surfaces listed on this label [Use to]]
 [Disinfects hard, non-porous surfaces in 60 seconds]
 [[Disinfects] hard surfaces [that people touch]]
 [Disinfects [health club equipment][treadmill handles][elliptical handles][exercise bike handles][weight benches]]
 [Disinfects [in [just] 60 seconds]]
 [nonylphenol ethoxylates free]
 [alkylphenol ethoxylates free]
 [Free of hormone disruptors]
 [Easy-to-use]
 [Easy [and convenient] way to disinfect [bathrooms][office][nursing stations][high touch] hard, non-porous surfaces everyday]
 [Effective daily cleaner]
 [Eliminates odors]
 [[Convenient] [portable] way to disinfect hard non-porous surfaces]
 [Saves Time]
 [Faster Contact Times]
 [[Kills TB in 60 seconds] [in presence of 5% bioburden [organic matter]]].
 [For daily use]
 [For use in critical care areas [where control of [the hazards of] cross contamination is of prime importance]
 [Fragrance Free]
 [Free of fragrance]
 [Fresh smell] [Helps prevent cross contamination on treated surfaces]
 [Hospital [disinfectant] [disinfection] [use only when hospital use sites on label]
 [Just] [Simply] [spray and wipe] [exterior toilet surface] [bathroom germs] [away]
 [[Kills bacteria in 20 seconds] [in presence of 5%bioburden [organic matter]]]
 [Kills viruses in 60 seconds (Canine Parvovirus)]
 [[Fungicidal in 10 seconds] [in presence of 10% bioburden [organic matter]]]
 [Kills odor causing bacteria]
 [[Kills viruses in 60 seconds] [in presence of 5% bioburden [organic matter]]]
 [Kills [or eliminates] 99.9999% of bacteria]
 [Kills [or eliminates] 99.9999% of viruses]
 [Kills [or eliminates] 99.9999% of fungus]
 [No mixing required]
 [Ready-To-Use]
 [Up to 6 log reduction]
 [Leaves [bathroom] [office] disinfected [and smelling fresh]
 [No fragrance added]

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[No measuring]
[No mixing]
[Odor [elimination] [neutralization]
[One step cleaner and disinfectant]
[Perfect for disinfecting exterior toilet surfaces - or - around the exterior toilet surface]
[Portable]
[Premixed] [Premeasured] [Fast] [Easy] [and convenient] way to disinfect]
[Ready-to-Use]
[Reduces] [risk of cross contamination] [on hard non-porous surfaces]
[Reduces] [packaging] waste [by X%] [when compared to regular canister or bucket or pail]
[Requires no mixing or measuring and are ready-to-use]
[Sample]
[Use to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization / high-level disinfection]
[Wipes out] [Kills] [common] [household] [bacteria] [viruses] [germs]
[Wipes out] [Kills] [Eliminates] [listed organisms] in [just] [60 seconds]
[Lime-Scented]
[Broad-Spectrum]❖
[Clean, Fresh Smell]
[SurfOL]
[Proprietary SurfOL colloid chemistry technology]
[SurfOL Technology]
[Biodegradable surfactants]
[With a bleach free formula]
[EcoPAK - Less Space - Less Waste]
[Fast, effective, and efficient application]
[Effective in clinical settings]
[Complete disinfection on hard, non-porous surfaces]
[Does not damage medical, dental, veterinary equipment]
Micrylium uses only USP Grade Ethanol and Biodegradable Surfactants

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{Note - the chart shown below shall be considered optional - e.g. inclusive in {bracket}}

[When used as directed, BioSURF provides effective Tuberculocidal** / Virucidal* / Bactericidal^X / Fungicidal^{XX} activity against the following organisms:]

**Tuberculocidal	Associated with:
Mycobacterium bovis (BCG)**	Tuberculosis (BCG)
Bactericidal^X	
Staphylococcus aureus ^X	Infections such as Meningitis and Carbuncles
Pseudomonas aeruginosa ^X	Infections of the pulmonary tract, urinary tract, burns, wounds, and also causes other blood infections
Salmonella enterica ^X	Food poisoning and gastroenteritis
*Virucidal	
Hepatitis B Virus (HBV)*	Hepatitis B infection related illnesses
Human Immunodeficiency Virus (HIV-1)*	AIDS
Canine Parvovirucidal*	
Fungicidal^{XX}	
Trichophyton mentagrophytes ^{XX}	Athletes Foot Fungus

❖ Indicates broad-spectrum as summarized in the table above



{Green team refers to the team (staff) of Micrylium Laboratories}